



**This electronic thesis or dissertation has been
downloaded from Explore Bristol Research,
<http://research-information.bristol.ac.uk>**

Author:
Rees, Gwen

Title:
Understanding Prescription Veterinary Medicine Use on UK Dairy Farms

General rights

Access to the thesis is subject to the Creative Commons Attribution - NonCommercial-No Derivatives 4.0 International Public License. A copy of this may be found at <https://creativecommons.org/licenses/by-nc-nd/4.0/legalcode>. This license sets out your rights and the restrictions that apply to your access to the thesis so it is important you read this before proceeding.

Take down policy

Some pages of this thesis may have been removed for copyright restrictions prior to having it been deposited in Explore Bristol Research. However, if you have discovered material within the thesis that you consider to be unlawful e.g. breaches of copyright (either yours or that of a third party) or any other law, including but not limited to those relating to patent, trademark, confidentiality, data protection, obscenity, defamation, libel, then please contact collections-metadata@bristol.ac.uk and include the following information in your message:

- Your contact details
- Bibliographic details for the item, including a URL
- An outline nature of the complaint

Your claim will be investigated and, where appropriate, the item in question will be removed from public view as soon as possible.



**This electronic thesis or dissertation has been
downloaded from Explore Bristol Research,
<http://research-information.bristol.ac.uk>**

Author:

Rees, Gwen

Title:

Understanding Veterinary Medicine Use on UK Dairy Farms

General rights

Access to the thesis is subject to the Creative Commons Attribution - NonCommercial-No Derivatives 4.0 International Public License. A copy of this may be found at <https://creativecommons.org/licenses/by-nc-nd/4.0/legalcode>. This license sets out your rights and the restrictions that apply to your access to the thesis so it is important you read this before proceeding.

Take down policy

Some pages of this thesis may have been removed for copyright restrictions prior to having it been deposited in Explore Bristol Research. However, if you have discovered material within the thesis that you consider to be unlawful e.g. breaches of copyright (either yours or that of a third party) or any other law, including but not limited to those relating to patent, trademark, confidentiality, data protection, obscenity, defamation, libel, then please contact collections-metadata@bristol.ac.uk and include the following information in your message:

- Your contact details
- Bibliographic details for the item, including a URL
- An outline nature of the complaint

Your claim will be investigated and, where appropriate, the item in question will be removed from public view as soon as possible.

Understanding Prescription Veterinary Medicine Use on UK Dairy Farms

Gwenllian Mair Rees

A dissertation submitted to the University of Bristol in accordance with the requirements for award of the degree of Doctor of Philosophy in the Faculty of Health Sciences

Bristol Vet School, October 2018

Word Count: 58,883

Abstract

Background: The way that prescription veterinary medicines (PVM) are used on UK dairy farms is currently poorly understood, despite the importance of understanding antimicrobial use in agriculture and its potential impact on antimicrobial resistance.

Methods: This research includes a cross-sectional study of PVM storage practices across 27 UK dairy farms, a method agreement analysis of the three most common ways to quantify on-farm use of PVM to determine the best measurement method and a qualitative ethnographic study exploring the values of dairy farmers and the on-farm context and culture in relation to the use of PVM.

Results: UK dairy farmers stored PVM in a broadly 'correct' way, although in varying quantities. Storage of expired and unlicensed medicines was common, and occasionally inappropriate medicines were present on farms. Veterinary sales data showed the best levels of both clinical agreement and reliability with a gold standard of the three measuring methods tested; medicine waste bins showed moderate agreement with the gold standard and on-farm medicine records did not agree with the gold standard for use, and, as such, are not an effective way of reliably measuring actual PVM use. The attitudes, values and contexts most relevant to medicine use practice can be broadly divided into four dominant themes: knowledge, trust, autonomy of treatment practice and a duty of care. The way these themes can impact on medicine use is not straightforward, and occasionally seem contradictory. It is important, however, to realise that changing medicine use practices requires an understanding of all factors involved in treatment decisions.

Discussion: This thesis demonstrates an important contribution to the scientific knowledge of veterinary medicine use through innovative methods and provides an evidence base from which to further develop models of treatment decision and behavioural intervention aimed at improving responsible medicine use alongside recommendations for policy makers.

Dedication

For The Dude, who we've yet to meet but already means the world.

Acknowledgements

"I may not have gone where I intended to go, but I think I have ended up where I needed to be."

- Douglas Adams, The Long Dark Tea-Time of the Soul

When I first embarked on this PhD journey, I had no idea how enjoyable it would be. You're told how hard a slog it is, how much it will wear you down, but I've not found that to be true for me. Though not always easy or straightforward, I've been lucky enough to have such a wonderful group of people supporting me that I've genuinely loved every day. I am not the same person who started out three years ago, and I do not have the same outlook on the world. I've benefitted enormously from the opportunity to study in such depth and I'm just so grateful to all those who have made it the experience it's been.

I would like to begin by thanking the one person who has spent almost as much of the last three years thinking about my thesis as I have – Dr. Kristen Reyher. Without your boundless enthusiasm, support, encouragement and advice this manuscript would likely not exist. You were the reason I began to pursue this PhD and have become the reason I want to remain in academia. I'm so glad to have you in my life, never change!

I'd next like to thank Prof. David Barrett for his guidance and leadership throughout my time at Bristol Vet School and for his patience while I find my academic feet. I really feel that I've found a mentor for the rest of my career, and that's a wonderful thing. I must also express my gratitude to Prof. Henry Buller, who has made a fantastic contribution to my supervisory team. While I'm sure my first forays into qualitative research must have been like watching Bambi on ice sometimes, he has encouraged me to stretch my thinking and really helped me to change my perspective. Prof Helen Lambert has provided invaluable training, advice and feedback at exactly the right times during my conversion to qualitative researcher. Also to Prof Alastair Hay, who's input at the design and concept

stage was invaluable and helped me see the parallels with human healthcare. I feel truly grateful for the time invested in my work.

To Elizabeth Coombes and the trustees of the Langford Trust for Animal Health and Welfare I can only say, with all sincerity, thank you. Your funding made this work possible, and I can only hope it will make a real difference to the work of farmers and vets. And, of course, I couldn't have done any of the work without the genuine enthusiasm of all of the farmers who participated. Despite having worked alongside dairy farmers for several years I never before truly appreciated the hard work, care and compassion required to be a farmer.

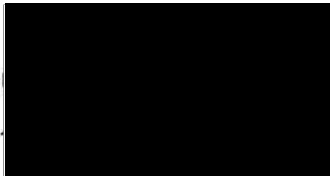
To Lisa, who has really changed me for the better in the last three years. I may still be a professional cynic, but these days I always ask myself "what would Lisa do?". The answer to this is of course always "Say yes to whatever it is and give it 110% while wearing bonkers leggings" and if that's not a motto for life I don't know what is. I also have to thank Alison, who has been there for me whenever I'm feeling those paradigm shift pains, ready with a willing and experienced ear to listen to and empathise with the hurdles of attempting a mixed-methods PhD. Andrea, Sarah, David T, Mick, Hannah, Emma, Ginny, Fernando, Tom, Jon, Andy, Liz, Dave, you've all contributed in ways both big and small and I thank you for that.

Away from the office, the support of family and friends has meant everything to me. Despite my decision to abandon a perfectly respectable career and become a full-time student again, not one of you questioned why but rather accepted the move as an inevitable consequence of my being Gwen. Mam, Dad, I genuinely couldn't have done it without either of you, it's that simple. Owz & Helen, for the perpetually open and welcoming London B&B&Gin service whenever I have had a last-minute meeting or conference. Victoria, Catherine, look how far we've come in the last 3 years! Mike, Louise, Holly, Sunil, Alastair, always ready to show me what true friends are really for. Lucy and Nathan for the dog-sitting, wine-drinking, chilli-eating goodness. Danny, for the company when I needed it the most and the never-ending laughs (not always intentional).

And finally, to Nick. By simply being you, and being there for me, you've given me the foundations I needed to build a thesis, a life and a family. You've shown me what's truly possible to achieve with your love and support. I can't wait for all of the adventures to come but as this PhD rollercoaster ends, I just know that we are so much greater than the sum of our parts. I love you.

I declare that the work in this dissertation was carried out in accordance with the requirements of the University's Regulations and Code of Practice for Research Degree Programmes and that it has not been submitted for any other academic award. Except where indicated by specific reference in the text, the work is the candidate's own work. Work done in collaboration with, or with the assistance of, others, is indicated as such. Any views expressed in the dissertation are those of the author.

SIGNE



DATE:

21/12/18

Table of Contents

Chapter 1	Introduction.....	1
1.1	Overview.....	3
1.2	Aim of this thesis.....	5
1.3	Thesis outline.....	6
Chapter 2	Literature review and thesis rationale	9
2.1	Abstract.....	11
2.2	Prescription Veterinary Medicines	12
2.2.1	Prescription veterinary medicines in the UK	12
2.2.2	Legislation and guidelines	15
2.2.3	Out of date products	18
2.2.4	Responsible antimicrobial use	22
2.3	Prescription Veterinary Medicine Use.....	28
2.3.1	Measuring medicine use	28
2.3.2	Antimicrobial use metrics.....	31
2.4	Farmer behaviour and decision making	35
2.4.1	Previous literature	35
2.4.2	Medicine-specific behaviour.....	38
2.5	Human medicine use.....	40
2.5.1	Measuring use.....	40
2.5.2	Decision making and medicine use behaviours	41
2.6	Knowledge Gaps.....	43
Chapter 3	Methodology and Methods.....	47
3.1	Abstract.....	49

3.2	Ontology and epistemology	50
3.3	Mixed methods research.....	51
3.3.1	Methodological Triangulation and Pluralism.....	52
3.3.2	Quantifying medicine use	53
3.3.2.1	Veterinary sales data	53
3.3.2.2	Medicine records	55
3.3.2.3	Medicine waste bins	56
3.3.3	Qualitative research	57
3.3.4	Ethnography	59
3.3.4.1	Semi-structured in-depth interviews	62
3.3.4.2	Participant observation	64
3.4	Theoretical framework.....	66
3.4.1	Grounded Theory	66
3.4.2	Thematic Analysis	67
3.4.3	Computer-Assisted Qualitative Data Analysis Software	68
3.5	Methods.....	68
3.5.1	Ethical approval	68
3.5.2	Selection and recruitment	69
3.5.3	Farm medicine audits.....	72
3.5.4	Semi-structured in-depth interviews	74
3.5.5	Participant observation	75
3.5.6	Piloting the research methods.....	76
Chapter 4 Resource availability: Investigating the contents of medicine cupboards		79
4.1	Abstract.....	81
4.2	Introduction	82
4.3	Methods.....	85
4.3.1	Data collection	85

4.3.1.1	Medicine database	85
4.3.1.2	Structured survey	86
4.3.1.3	Medicine Inventory	87
4.3.2	Data analysis	88
4.4	Results.....	89
4.4.1	Farm Demographics	89
4.4.2	Storage methods & labelling	91
4.4.3	Prescription Veterinary Medicines.....	92
4.4.3.1	Antimicrobials	93
4.4.3.2	Vaccines & Other PVM	96
4.4.4	Expired medicines	97
4.4.5	Cascade medicines	97
4.5	Discussion and Conclusions.....	98
4.5.1	Antimicrobial storage	99
4.5.2	Labelling.....	100
4.5.3	Expired medicines	101
4.5.4	The Cascade	103
4.5.5	Study limitations	103
4.5.6	Implications for medicine use.....	104
4.5.7	Future research.....	105
Chapter 5	Measuring prescription veterinary medicine use: a longitudinal method comparison study.....	107
5.1	Abstract.....	109
5.2	Introduction	110
5.3	Methods.....	112
5.3.1	Data handling.....	112
5.3.2	Defining a “gold standard”	113

5.3.3	Medicine waste bins.....	115
5.3.4	Veterinary sales data.....	117
5.3.5	On-farm medicine records.....	118
5.3.6	Classification of PVM.....	118
5.4	Data analysis	119
5.5	Results and discussion.....	123
5.5.1	Type of PVM measured	124
5.5.1.1	Injectable antimicrobials	124
5.5.1.2	Intramammary antimicrobials	130
5.5.1.3	Other antimicrobials.....	133
5.5.1.4	All injectables	135
5.5.1.5	Vaccines	137
5.5.1.6	Teat sealants	139
5.5.2	Method of measurement	143
5.5.2.1	Veterinary Sales Data	143
5.5.2.2	Medicine waste bins.....	144
5.5.2.3	On-farm medicine records.....	145
5.5.3	Limitations	146
5.6	Conclusions	149
5.6.1	Future work	149
5.6.2	Policy implications.....	150
Chapter 6	Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices	151
6.1	Abstract.....	153
6.2	Introduction	154
6.3	Materials and Methods.....	156
6.3.1	Semi-structured in-depth interviews	157
6.3.2	Participant observation	164

6.3.3	Data Analysis.....	167
6.4	Results and Discussion	167
6.4.1	Knowledge	168
6.4.1.1	Experiential knowledge	168
6.4.1.2	Experimental knowledge	171
6.4.1.3	Uncertainty	172
6.4.1.4	Knowledge conceptualisation	174
6.4.2	Trust	176
6.4.2.1	Trust in the veterinary surgeon.....	176
6.4.2.2	Trust in the staff	179
6.4.2.3	Trust in the medicine.....	181
6.4.2.4	Trust in the animal	182
6.4.2.5	Trust in the data	184
6.4.3	Autonomy of treatment practice	185
6.4.3.1	Regulatory frameworks	186
6.4.3.2	Farming this farm	190
6.4.3.3	Physical resources	192
6.4.3.4	Decision hierarchy	193
6.4.4	A duty of care.....	195
6.4.4.1	The bovine patient	196
6.4.4.2	Treatment as action	197
6.5	Conclusions	200
6.5.1	Study limitations	201
6.5.2	Policy implications & future research	204
Chapter 7	Conclusions.....	209
7.1	Summary of findings	212
7.2	Contribution to scientific knowledge	213
7.3	Limitations	217
7.4	Further work	219
7.5	Policy implications and practical impact	221

References	227
Appendix 1: Participant information leaflet for medicine audit farms	243
Appendix 2: Participant information sheet for farms undergoing participant observation	246
Appendix 3: Consent form.....	249
Appendix 4: Farmer recruitment leaflet (North Somerset).....	250
Appendix 5: Structured farm management and demographic questionnaire	251
Appendix 6: Initial visit checklist	256
Appendix 7: Medicine bin reminder signs placed on participating farms	257
Appendix 8: Bin Audit Farm visit checklist	259
Appendix 9: Semi-structured in-depth interview topic guide	260
Appendix 10: Screenshot of prescription veterinary medicine database for medicines licensed for use in cattle, adapted from the veterinary medicines directorate’s product information database.....	262
Appendix 11: Screenshot example of farm medicine audit database developed for data entry of prescription veterinary medicines during medicine cupboard inventories and medicine waste bin audits.....	263
Appendix 12: Individual farm medicine audit reports example	264

List of Figures

Figure 4-1: Medicine storage locations on the 27 participating farms	92
Figure 4-2: Total quantity of antimicrobial stored in mg per population corrected unit (PCU) for each of the 27 participating farms	95
Figure 4-3: Total quantity of antimicrobial stored in mg per lactating cow on each of the 27 participating farms.....	95
Figure 4-4: Total quantity of antimicrobial stored in mg per 1000 litres of milk produced annually on each of the 27 participating farms	96
Figure 5-1. Bland-Altman plot comparing veterinary sales data with gold standard data for injectable antimicrobials in total ml.....	125
Figure 5-2. Bland-Altman plot comparing medicine waste bin data with gold standard data for injectable antimicrobials in total ml.	125
Figure 5-3. Bland-Altman plot comparing veterinary sales data with gold standard data for intramammary antimicrobials in total number of tubes.	131
Figure 5-4: . Bland-Altman plot comparing transformed medicine waste bin data with gold standard data for intramammary antimicrobials in total number of tubes.....	131
Figure 5-5. Bland-Altman plot comparing veterinary sales data with gold standard data for all injectable prescription veterinary medicines in total ml.....	135
Figure 5-6. Bland-Altman plot comparing medicine waste bin data with gold standard data for all injectable prescription veterinary medicines in total ml.....	136
Figure 5-7. Bland-Altman plot comparing veterinary sales data with gold standard data for vaccines in total number of doses.	137
Figure 5-8. Bland-Altman plot comparing medicine waste bin data with gold standard data for vaccines in total number of doses.	138
Figure 5-9. Bland-Altman plot comparing veterinary sales data with gold standard data for teat sealants in total number of tubes.....	140

List of Tables

Table 4:1: Demographic and management characteristics of the 27 participating farms	90
Table 4:2: Production, health and medicine storage characteristics of the 27 participating farms	91
Table 4:3: Total quantities of antimicrobial stored across all 27 participating farms, by route of administration	93
Table 4:4 Total quantity of antimicrobial stored on all 27 participating farms.....	94
Table 5:1 Tests and transformations used to investigate whether there was a systematic difference between the mean medicine use measured by three different recording methods when compared with a gold standard measure in a farm-level sample.....	121
Table 5:2: Descriptive statistics of the quantities of different medicine types recorded across all participating farms over the 12 month period (n=26), by the three different recording methods.....	123
Table 5:3 Bland-Altman Plot statistics for all comparison of medicine use recording methods. ..	127
Table 5:4. Intraclass correlation coefficients and statistical interpretation of reliability comparing veterinary sales and medicine waste bin data with the gold standard for the different medicine types. Statistical interpretation is based on:	129
Table 5:5. Clinical interpretation of limits of agreement for each medicine type and recording method, when compared with the median total quantity for that medicine on each farm (n=27) as recorded by the gold standard. Based on differences of:	130
Table 6:1 Summary of participant characteristics for semi-structured in-depth interviews (n = 20)	163
Table 6:2 Summary of farm characteristics for participant observation farms (n = 3)	165

List of Abbreviations

AD	-	Professor Andrew Dowsey
ADD	-	Average Daily Dose
ADQ	-	Average Daily Quantity
AHDB	-	Agriculture and Horticulture Development Board
AMTRA	-	Animal Medicines Training Regulatory Authority
AMU	-	Antimicrobial use
ANOVA	-	Analysis of Variance
AVM-GSL	-	Authorised veterinary medicine: general sales list
BCVA	-	British Cattle Veterinary Association
bTB	-	Bovine tuberculosis
BVA	-	British Veterinary Association
BVD	-	Bovine viral diarrhoea
CAQDAS	-	Computer Assisted Qualitative Data Analysis
CCG	-	Clinical Commissioning Group
CD	-	Controlled drug
DB	-	Professor David Barrett
DDD	-	Defined Daily Dose
DEFRA	-	Department for the Environment, Fisheries and Rural Affairs
EMA	-	European Medicines Agency
eMB	-	Electronic medicine book
ESVAC	-	European Surveillance of Veterinary Antimicrobial Consumption
EU	-	European Union
FDA	-	Food and Drug Administration
FSV	-	Dr. Fernando Sanchez-Vizcaino Buendia
GG	-	Dr Ginny Gould
GI	-	Gastrointestinal
GR	-	Gwen Rees (author)
HB	-	Professor Henry Buller
HL	-	Professor Helen Lambert
HP-CIA	-	Highest-Priority Critically Important Antimicrobials

Formatted: Portuguese (Brazil)

Formatted: German (Germany)

HS	-	Hannah Schubert
ICC	-	Intraclass Correlation Coefficient
IT	-	Information Technology
KR	-	Dr. Kristen Reyher
LM	-	Lisa Morgans
mg	-	milligram
MRL	-	Maximum Residue Limits
NFA-VPS	-	Non-food animal: veterinary surgeon/pharmacist/SQP
NHS	-	National Health Service
NOAH	-	National Office for Animal Health
NSAID	-	Non-steroidal anti-inflammatory drug
PCU	-	Population-corrected unit
POM-V	-	Prescription-only medicine: veterinary surgeon
POM-VPS	-	Prescription-only medicine: veterinary surgeon/pharmacist/SQP
Ppl	-	pence per litre
PVM	-	Prescription veterinary medicine
RCVS	-	Royal College of Veterinary Surgeons
RUMA	-	Responsible Use of Medicines in Agriculture Alliance
SD	-	Standard deviation
SLEP	-	Shelf-life extension programme
SPC	-	Summary of Product Characteristics
SQP	-	Suitably qualified person
TORA	-	Theory of Reasoned Action
TpB	-	Theory of Planned Behaviour
UK	-	United Kingdom
UoB	-	University of Bristol
USA	-	United States of America
VARSS	-	Veterinary Antimicrobial Resistance and Sales Surveillance
VMD	-	Veterinary Medicines Directorate
WHO	-	World Health Organisation

Chapter 1 Introduction

Introduction

1.1 Overview

Prescription veterinary medicine (PVM) use in UK agriculture is a subject that has come under increasing scrutiny over the past decade. This has been largely driven by a growing global awareness of the threat posed by antimicrobial resistance to the human population, as illustrated by the following quote:

“We have reached a critical point and must act now on a global scale to slow down antimicrobial resistance.”

– Professor Dame Sally Davies, UK Chief Medical Officer

Antimicrobials have been used in agriculture almost since their inception, and their use to treat bacterial infection has historically been intertwined with prophylaxis and have even been used for growth promotion. Although antimicrobial resistance (AMR) in the UK has been recognised as a problem for several decades, progress in reducing the use of antimicrobials in agriculture and a push towards more responsible antimicrobial use (AMU) is relatively recent and was driven in the UK in part by the government-commissioned independent review on AMR, published in 2016 and led by Lord Jim O’Neill, so known as the O’Neill Report (O’Neill, 2016). This report made several recommendations, two of which were aimed specifically at the use of antimicrobials in agriculture: to improve global surveillance of drug resistance and antimicrobial consumption in humans and animals, and to reduce unnecessary use of antimicrobials in agriculture and their dissemination into the environment. Since its publication, the political and public pressure to reduce AMU in farmed animals in the UK has increased, and the industry has responded through numerous initiatives aimed at improving responsible use (this will be discussed in detail in Chapter 2).

Introduction

Whilst improving the measurement and understanding of AMU in order to reduce consumption in agriculture is arguably the most important goal, understanding the use of all PVM on farms gives a more complete picture. The use of antimicrobials is inextricably linked to the use of other PVM such as anti-inflammatories, vaccines and mechanical teat sealants, and, as such, attempting to understand and change the use of one without the others is likely to have limited impact. As outlined in the literature review in Chapter 2, there is a lack of scientific evidence on the use and storage of non-antimicrobial PVM or the combined use of antimicrobials and other PVM. Therefore, this thesis argues that by considering all PVM together, the resulting knowledge gain is likely to be greater than the sum of its parts.

The dairy industry is the third largest user of veterinary antimicrobials in UK livestock agriculture, after the poultry and pig industries (Veterinary Medicines Directorate, 2018c). In 2016 (the time period during which much of the research in this thesis was conducted), the UK dairy industry comprised approximately 13,200 farms, with a total population of 1.9 million adult milking cows and an average herd size of 143 (Agriculture and Horticulture Development Board, 2016, Department for Environment Fisheries and Rural Affairs, 2018). The total UK milk production was 14.96 billion litres with the average yield standing at 7559 litres per cow per year (Agriculture and Horticulture Development Board, 2016). In 2016, the average milk price was 22.7 pence per litre (ppl) while the cost of production for 2016/2017 was 25.5 ppl, meaning that on average, UK dairy farmers were losing 2.8 pence for every litre of milk produced. Understanding the on-farm context, including economic and market pressures such as these, is vital if we are to comprehend the motivations behind treatment practices.

1.2 *Aim of this thesis*

This research explored the ways in which PVM were being stored, measured and used on UK dairy farms. It builds on and contributes to the body of work on the use of PVM in agriculture, specifically in the UK dairy industry. The current literature has tended to focus on quantitative surveys and measurements of AMU through on-farm treatment records, medicine waste bins or veterinary sales data. A dearth of truly qualitative work investigating medicine-use behaviours has been identified, as discussed in Chapter 2. To the author's knowledge there have been no studies examining the way in which PVM are stored on UK dairy farms, and it is postulated that this may be a significant factor in understanding the use of PVM on-farm. There is also a lack of research to validate the use of veterinary sales data, on-farm medicine records or medicine waste bins as proxies for actual use despite a recent move towards using veterinary sales data for AMU surveillance by the Veterinary Medicines Directorate (VMD) (Veterinary Medicines Directorate, 2017, Veterinary Medicines Directorate, 2018c).

This thesis aims to provide some of the data necessary to begin addressing this knowledge gap. The research described within aimed to address that knowledge gap by using a mixed-methods approach to investigate the following research questions on UK dairy farms:

- i. How are PVM being stored on UK dairy farms?
- ii. Can veterinary medicines sales data, on-farm medicine records or medicine waste bins be used to accurately estimate on-farm medicines use on the study farms?
- iii. What are the values and practices of dairy farmers and what are the on-farm contexts affecting medicine use practice on UK dairy farms?

Introduction

This thesis utilises qualitative research and ethnographic techniques to better understand PVM use in dairy cattle and combines this data with quantitative work examining PVM storage and the way in which PVM use is measured. The analytic focus of this thesis on resource availability, recording methods, qualitative interviews and observational data provides an important contribution to the literature on veterinary medicine use in agriculture.

1.3 *Thesis outline*

This thesis is divided into seven chapters. The first three chapters provide an introduction to the thesis, the context of the research problem and the methodology and methods used. The next three chapters describe three separate research studies aimed at addressing each of the three research questions of the thesis. The final chapter brings together the overall outcomes of the thesis and discusses its implications on the future of policy and research in the area.

The outline of the thesis is as follows:

Chapter 2: This chapter provides an introduction to the context within which this thesis was written and lays out the thesis rationale. It provides a background on the legislation and current use of PVM in the UK and leads on to a critical review of the major literature currently available in this area. This literature review spans PVM use, approaches to the understanding of farmer decision making and behaviour, and some of the major literature available in human health research which can be used to inform knowledge in the area of medicine use behaviours. Following on from this, the limitations in the available literature are used to identify the knowledge gaps that have informed the development of this work.

Chapter 3: This thesis uses a mixed-methods approach to understanding PVM use, and Chapter 3 introduces the research paradigm and the methodological basis for the work. The strengths and limitations of mixed-methods research are described and the validity for the nature of this enquiry is justified. Additionally, this chapter outlines the research methods used to answer each of the three main research aims of the thesis and the pilot work used to inform these methods.

Chapter 4: On-farm storage of PVM, this chapter argues, plays an important role in the use practices of PVM. Farmers are constrained or enabled by the resources available to them, in this case the medicine resources available on farm. Through a cross-sectional study of veterinary medicine cupboards on the participating farms, Chapter 4 describes the ways in which farms were storing their PVM, the composition of the types of PVM being stored and the quantities stored.

Chapter 5: The accurate measurement of PVM use has implications for informing the wider One Health agenda as well as impacting on agricultural policy, benchmarking and targets. This is explored in Chapter 5 by measuring on-farm use through medicine waste bin auditing, veterinary sales data and on-farm medicine treatment records, and comparing these data with a pre-determined 'gold standard' measure of actual use through a longitudinal method comparison study.

Chapter 6: This substantial chapter uses an ethnographic approach in order to begin to describe and understand UK dairy farmer motivations, values, drivers, behaviours and practices surrounding the use of PVM in cattle. Through a combination of semi-structured in-depth interviews with 20 dairy farmers and a year-long participant observation of three

Introduction

dairy farms, this chapter explores thematically the way in which participating farmers' motivations and values affected their medicine use practices.

Chapter 7: The overall conclusions of the entire body of work are chronicled in Chapter 7, along with the potential impact and policy implications of the thesis. This chapter also suggests further work that could lead on from this research and discusses the future of research in this area.

Chapter 2 Literature review and thesis rationale

Literature review and thesis rationale

2.1 *Abstract*

This literature review has been divided into four sections, each giving an overview of the current literature and providing the context from and within which this thesis has emerged. The first section will discuss the background of prescription veterinary medicines (PVMs), and the UK legislation and guidelines that form the framework in which veterinary surgeons and dairy farmers must operate. The second section gives an overview of some of the ways in which PVMs have been measured, benchmarked and reported (in the UK and internationally) by governments and by research scientists. This includes a discussion of the strengths and limitations of measuring and reporting use in these ways, the importance of reliable data on antimicrobial use and the paucity of data on non-antimicrobial medicine use. The third section gives an outline of the large body of literature available on farmer behaviour and decision making and goes on to examine more specifically the literature on behaviour and decision making relating to medicine use in livestock. Finally, there is a review of some of the major literature from the human health sector focussed on medicine prescribing decisions in primary care and on patient compliance.

Following on from these overviews, this chapter discusses the knowledge gaps that have been identified from the literature and describes the research questions that have emerged, and which form the basis of this thesis.

2.2 *Prescription Veterinary Medicines*

2.2.1 Prescription veterinary medicines in the UK

Veterinary medicines in the UK are defined by the Veterinary Medicines Regulations 2013 as “any substance or combination of substances presented as having properties for treating or preventing disease in animals; or any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.” - Veterinary Medicines Regulations 2013 (S.I. 2033) Section 2.1 (b).

Veterinary medicines are further categorised into different classes:

POM-V: These medicines can only be supplied on prescription by a veterinary surgeon.

POM-VPS: These medicines can only be supplied on prescription by a Registered Qualified Person (i.e. a veterinary surgeon, pharmacist or Suitably Qualified Person, SQP).

NFA-VPS: These medicines for non-food producing animals may be supplied by a veterinary surgeon, a pharmacist or SQP without prescription.

AVM-GSL: These medicines have no restrictions and are commonly called ‘over the counter medicines’ (Royal College of Veterinary Surgeons, Updated 2018).

According to the Veterinary Medicines Directorate (VMD) published list (Veterinary Medicines Directorate, 2018b) in the UK as of 1st January 2018 there were 1876 POM-V class medicines, of which 142 were licensed solely to treat cattle and 455 were licensed to treat multiple species including cattle. These include antimicrobials, hormones, anti-

inflammatories (i.e. non-steroidal anti-inflammatory drugs [NSAIDs] and corticosteroids), some vitamin and mineral preparations, neurological agents and miscellaneous other drugs.

There were 233 different antimicrobial preparations licensed for use in cattle, of which a total of 75 were classed as highest-priority critically important antimicrobials (HP-CIA) to human health. The World Health Organisation (WHO) produce a list of antimicrobials considered of critical importance to human medicine for the purposes of risk management and responsible antimicrobial use in the face of global antimicrobial resistance (World Health Organisation, 2016). The 2017 revision contains some antimicrobials licensed for use in cattle, specifically fluoroquinolones, 3rd and 4th generation cephalosporins, macrolides, and colistin (licensed for use in calves). However, the European Medicines Agency (EMA) to date only classify fluoroquinolones, colistin and 3rd and 4th generation cephalosporins as HP-CIA (European Medicines Agency, 2014). For the purposes of this thesis, the EMA definition of HP-CIA was used and, as such, macrolides were not considered to be HP-CIA. In cattle, there were 43 fluoroquinolones, 19 3rd generation cephalosporins and 12 4th generation cephalosporins licensed for use at the time of this study along with five colistin products licensed for calves. All fluoroquinolones were in injectable form, two 3rd generation cephalosporins were intramammary preparations and the other 17 were injectable. Seven 4th generation cephalosporins were intramammary preparations leaving five injectable solutions. Four colistin products were oral solutions, the remaining product was an oral powder.

For those non-antimicrobial medicines licensed for use in cattle, there were 57 anti-inflammatories, 21 hormones, 43 vaccines, 31 neurological agents (sedatives, local

anaesthetics, etc.), 11 anti-protozoals, nine vitamin/mineral preparations, one endectocide and miscellaneous other drugs.

At the time of the study there were 66 controlled drugs (CDs) listed in Schedules 1-5 of the Misuse of Drugs Regulations 2001 S.I. 3998 (Secretary of State, 2001) and licensed for use in animals in the UK: 16 Schedule 2 medicines, 35 Schedule 3 medicines and 15 Schedule 4 medicines. Of these 66 CDs, 16 were licensed for use in cattle: three Schedule 2 medicines, nine Schedule 3 medicines and five Schedule 4 medicines. Veterinary medicines only contain CDs in Schedules 2-5 and only those in Schedule 2 and 3 are subject to additional storage and prescription requirements. The Schedule 2 and 3 controlled drugs available for use in cattle were those used for euthanasia (cinchocaine hydrochloride, secobarbital chloride solution and pentobarbital sodium) or for anaesthesia (ketamine). These medicines should not be left on farm for use by the farmer and should only be used by a veterinary surgeon.

There were 319 POM-VPS medicines licensed in the UK, of which 158 held a license for treatment of cattle. These included most anthelmintic (worming) treatments and some vaccines. These medicines can be sold by SQPs through non-veterinary outlets and by human pharmacists, and veterinary practices will often have SQPs as part of the staff in order to prescribe and dispense POM-VPS medicines without the need for a veterinary surgeon's authorisation. The SQP status requires training and examination followed by registration through the Animal Medicines Training Regulatory Authority (AMTRA). There are currently around 7000 SQPs registered in the United Kingdom (Veterinary Medicines Directorate, 2018a).

2.2.2 Legislation and guidelines

Prescription veterinary medicines are subject to many regulations in the United Kingdom, and the government body with responsibility for maintaining these standards is the VMD. The use of PVMs in the UK is legislated through the Veterinary Medicines Regulations 2013 and comes under several EU Directives (European Union, 2009).

Prescription veterinary medicines in cattle must be licensed for use in that species, with licensing applied for by the pharmaceutical company manufacturing the PVM. The drug must also have a published Maximum Residue Limit (MRL) (European Union, 2009) which is used to set a milk and meat withdrawal time: the length of time after which the meat or milk is safe for human consumption (Veterinary Medicines Directorate, 2014b). For PVMs licensed in cattle, medicines must state the meat and milk withdrawal periods during which time it is illegal for the meat or milk to enter the human food chain. These withdrawal periods apply only when the product is used according to the use recommendations laid out in the summary of product characteristics (SPC) and product datasheet. In some cases, PVMs may be licensed only in cattle that are not producing milk. In the event that there is no suitable product licensed for use in a species or licensed for use to treat a specific diagnosed disease, veterinary surgeons may prescribe another drug according to the Prescribing Cascade (Veterinary Medicines Directorate, 2015b). This allows for veterinary surgeons to 'cascade' to medicines licensed in the correct species but for treating a different disease or, failing that, to medicines licensed for treating different species. The use of medicines licensed in cattle for the disease in question but used in a way which differs from that laid out in the datasheet is also considered Cascade use. In the case of food-producing animals, use of the Cascade is only allowed where those PVM being cascaded to have published MRLs (European Union, 2009). Where medicines

are prescribed under the Cascade the longer of the two following withdrawal periods should be observed; the minimum statutory meat and milk withdrawal periods (28 days and 7 days respectively) or the withdrawal period set out in the SPC (Veterinary Medicines Directorate, 2015b).

According to the Veterinary Medicines Regulations 2013, veterinary surgeons may only prescribe PVM to “animals under their care”. Due to a perceived lack of clarity the Royal College of Veterinary Surgeons (RCVS), the professional regulating body for veterinary surgeons, published guidelines with their interpretation of what “animals under their care” meant which state that:

“The veterinary surgeon must have been given the responsibility for the health of the animal or herd by the owner or the owner's agent, that responsibility must be real and not nominal, the animal or herd must have been seen immediately before prescription or recently enough or often enough for the veterinary surgeon to have personal knowledge of the condition of the animal or current health status of the herd or flock to make a diagnosis and prescribe and the veterinary surgeon must maintain clinical records of that herd/flock/individual” (Royal College of Veterinary Surgeons, Updated 2018, Section 4.9).

In practical terms, this threshold is likely to be exceeded on most dairy farms due to the nature of the farming system usually requiring semi-regular veterinary visits. However, in beef and sheep farming it is often the case that veterinary surgeons only visit the farm on an annual basis to meet the requirements for prescribing. Veterinary surgeons are required to keep records of all prescriptions and PVM sales, including information about the farm, the species for which it was prescribed, the quantity and the date. There is

currently no standardised format for this and there are many different practice management software packages that maintain these records. Although there is no legal requirement for veterinary surgeons to dispense PVM which have been labelled, the RCVS and the VMD consider it good practice. The Veterinary Medicines Regulations 2013 states that labels should contain the name and address of the recipient and the veterinary practice, the animal(s) intended for treatment, the date, medicine name, quantity, strength and the treatment instructions, expiry date of the medicine, meat and milk withdrawal period, batch number and the phrase "For animal treatment only" (Veterinary Medicines Regulations, 2013).

The Veterinary Medicines Regulations 2013 also lay out the legal requirements for medicine record-keeping by owners of food-producing animals. Records must contain the name of the product, quantity and the batch number, the date of acquisition and the name and address of the supplier. At the time of administration, the name of the product, quantity, date, withdrawal period and identity of animal(s) treated must be recorded, and if medicines are discarded, records of the unused medicines must also be kept of the quantity, date and method of disposal. These records should be kept on the premises for five years.

Ninety-eight percent of UK dairy farms are registered with the Red Tractor Farm Assurance Scheme (Responsible Use of Medicines in Agriculture Alliance, 2017), with a few other less common schemes also available. These schemes are voluntary; however, it is often a requirement of milk-buying companies that their suppliers participate in assurance schemes. These schemes were introduced as a quality assurance method to audit farms and ensure that they were meeting certain animal health, welfare, hygiene

and management criteria set by the regulatory body (Red Tractor Assurance, 2017). The schemes have a variety of different requirements and in general require an annual or 18-monthly visit from a farm assurance assessor who will audit the farm's records, management practices and other details depending on the requirements of that specific scheme.

One of the stipulations of most farm assurance schemes is that farms keep records of PVM treatments given to cattle. These records are expected to be complete and made available to the assessor upon farm assurance audit. The most common method for auditing the medicine records is by visualising the records and selecting a specific animal to view the treatments it has received during the audit period.

The government Code of Practice for Responsible Use of Medicines on Farm provides guidelines on storing medicines safely including the need to store veterinary medicines in lockable medicine cupboards or refrigerators, as appropriate, on farms (Veterinary Medicines Directorate, 2014a). Farm assurance audits include assessment of storage practices (Red Tractor Assurance, 2017).

2.2.3 Out of date products

All PVM are dispensed with a batch number (for traceability) and an expiry date. This expiry date is determined by the manufacturer based on efficacy testing, however it is not necessarily reflective of the date at which point the efficacy decreases; it is more accurate to describe this date as the latest date at which a positive efficacy test was conducted. It is not necessarily in the interests of the pharmaceutical companies to have extended shelf-lives for their products, and testing is expensive. There is therefore a balance to be reached between achieving a satisfactory shelf life that veterinary practices and farmers

are willing to store the medicines for use at a later date and a short enough shelf life that extensive efficacy testing is minimised.

According to the VMD "It is illegal to supply a product (even if free of charge) after the expiry date shown on the pack. Any out of date products should be disposed of in accordance with the wording on the product literature.

Some products (for example injectables), once they are opened, must be discarded after a period of time stated on their packaging. This is due to EU and national legislative requirements to ensure the stability and safety of the product. The expiry date is usually 28 days after opening but it can be shorter or longer." (Veterinary Medicines Directorate, 2015c, Section: Out of Date Products)

While it is illegal to supply an expired product, their presence is still common on farms (Chapter 4). This is largely due to medicines expiring through lack of use within the available window. Although storing medicines on farm for use at a later date is common practice, some medicines which are used less often are at higher risk of expiring before they have been used. It is not illegal for a farmer to use expired medicines for her/his animals, however this would technically be classed as unlicensed use, hence minimum statutory meat and milk withdrawal periods should be observed as described by the VMD (Veterinary Medicines Directorate, 2015b). The presence of expired antimicrobials is one of the points often checked during a farm assurance visit, therefore farmers are aware that they should not be present on farm. There is, however, a lack of any published data about the use or disposal of expired PVM on farms, either in the UK or internationally.

There is equally very little literature on the efficacy (or lack thereof) of expired medicines in the veterinary or the human medical spheres. It is commonly and logically assumed that with increased time after manufacture the efficacy of a product would decrease. However, the stability of different active ingredients means the rate of decrease should vary between medicines. Expiry dates for drug products are set based on real-time stability testing at appropriate storage conditions to determine whether the drug substance meets its individually set specification (European Medicines Agency, 2003). A specification “establishes the set of criteria to which a drug product should conform to be acceptable for its intended use” (European Medicines Agency, 1999, Bottom of page 14).

Information on stability of products beyond the expiry date is scant. The US Food and Drug Administration (FDA) ran a shelf-life extension program (SLEP) which produced evidence that many medicines have stability beyond their stated expiry date, although this stability is highly variable (Lyon et al., 2006). The author is unaware of any comparable literature on long-term stability of veterinary medicines beyond their labelled expiry date.

Perhaps of more practical importance than the expiry date stated on PVM is the shelf-life once broached. While this is often 28 days for injectable products and 24 hours for vaccines, anecdotally dairy farms rarely observe these expiry dates due to most injectable medicines being sold in 100 ml or 250 ml multi-dose bottles, and individual animals' treatment courses requiring varying volumes of medicine, for instance a one-off dose of 12 ml. This type of dose would leave 88 ml of product with a shelf-life of 28 days, during which time it is, in the author's experience, unlikely that the medicine would be used entirely. While anecdotally it seems that these broached expiries are not observed in practice on farms, there is currently no published literature about the compliance with

broached expiries. Similarly, for vaccines - whose shelf-life once broached is usually within 24 hours – a broached multi-dose bottle would need to be used within one day. This can make vaccination schedules (which often require small groups of animals to be vaccinated according to a reasonably strict calendar on different days) difficult to design. In recent years pack size options have improved and a farmer can now buy vaccines in packs of five, 10, 25, 50 or 100 doses, which is assumed to have resulted in less waste.

The reason for a broached expiry date is the fact that once a bottle's rubber seal has been broached with a needle, it can no longer be guaranteed to be sterile. The contamination of PVM with bacteria may lead to decreased microbiological stability and growth of bacterial colonies and is therefore more likely to be a cause for concern than the presence of sealed but expired medicines (Metcalf, 2009).

The storage temperature of medicines is another important variable which can affect shelf-life and stability. Most veterinary medicines are required to be stored at temperatures not exceeding 25°C and most refrigerated medicines require storage between +2°C and +8°C (National Office of Animal Health, 2018b). In the United States, research has shown that storage conditions regularly exceed the recommended temperature ranges during the summer months (Ondrak et al., 2015). In the UK, a study of on-farm refrigerator temperatures found that the majority failed to maintain the correct temperature range over an eight-month period, meaning the quality of medicines which require refrigeration such as vaccines would deteriorate (Williams and Paixao, 2018).

Loss of pharmaco-chemical stability is a problem for a number of reasons. The first is, of course, the reduced effect of the medicine which is in itself a welfare concern, particularly where it leads to lack of pain relief or treatment of disease. Reduced efficacy of antimicrobials is also a concern due to the presumed effect on the development of antimicrobial resistance (AMR). Where a dose of antimicrobial is given, if that antimicrobial is less efficacious, then there may be an unintended relative under-dosing of the product. Under-dosing can increase the pressure for selection of resistant organisms and therefore increasing the risk of development of AMR (O'Neill, 2016).

2.2.4 Responsible antimicrobial use

In order to understand the way in which PVMs are being used it is important to first understand the context within which dairy farmers are operating. While there are numerous guidelines and legislations in place regulating the purchase, storage, administration and recording of PVMs as described previously, more recently the global threat of AMR has caused a shift in focus in the agricultural industry towards reduced and defensibly responsible antimicrobial use. Responsible antimicrobial use is defined by the British Veterinary Association (BVA) as "Correct antimicrobial: As little as possible, as much as necessary" (British Veterinary Association, 2015, Top of page 1).

As mentioned earlier, the WHO have produced a list of all the classes of antimicrobials available in both human medicine and agriculture and have classified these antimicrobials according to their importance to human medicine (World Health Organisation, 2016). In practical terms for UK agriculture, the WHO classifications of the HP-CIA specifically involve the use of 3rd and 4th generation cephalosporins, fluoroquinolones, colistin and macrolides. The EMA's decision not to include macrolides in their list of HP-CIA has a

significant impact on the UK situation because macrolides (particularly those which are used for their long-acting properties) are commonly used in UK livestock agriculture. The decision of the EMA not to include macrolides is justified based upon the common and historical use of macrolides as a first-line treatment against a number of animal diseases (European Medicines Agency, 2011). However, the EMA recognises the importance of minimising the use of macrolides where possible.

Of the HP-CIAs defined by the EMA, all have historically been in common use in UK agriculture, and with the exception of colistin this is particularly true in the dairy sector. This is in part due to the licensing of parenteral ceftiofur, a 3rd generation cephalosporin which carries a zero-hour milk withdrawal period, as a treatment for numerous diseases in cattle. The use of HP-CIAs is therefore often cost-effective as using them negates the need for discarding milk following treatment. From a management perspective, using an antimicrobial with a zero-hour milk withdrawal period frees the farmer from needing to “dump” milk – removing milk from the human food-chain to safeguard against antibiotic residues – and enables milking to occur smoothly without the risk of human error leading to milk containing antimicrobials contaminating the bulk tank. HP-CIA were heavily marketed to both veterinary surgeons and farmers until recently, however an increasing awareness of the importance of HP-CIA among both veterinary surgeons and farmers combined with an increased top-down pressure from government and various stakeholders led to a 50% reduction of the use of HP-CIAs in UK dairy sector between 2015 and 2017 (Veterinary Medicines Directorate, 2017). As of 1st October 2013, it was no longer legal to advertise antimicrobials to professional keepers of animals (Veterinary Medicines Directorate, 2015a).

It has also been the case that some HP-CIAs (marbofloxacin, cefquinome) have historically been the only products licensed to treat certain conditions in dairy cattle, therefore in theory a veterinary surgeon could only prescribe HP-CIA where this disease was diagnosed in order to conform to the Veterinary Medicines Regulations 2013. The RCVS and VMD have since clarified that responsible prescribing of antimicrobials is a valid reason for using the Cascade in order to prescribe different, non-HP-CIAs in these cases.

In 2016 the O'Neill Report on AMR, a UK-funded independent report on antimicrobial resistance, concluded that although the use of antimicrobials in humans was the greatest driver of AMR in humans, agricultural use was also very important, and improvements needed to be made (O'Neill, 2016). This report specifically highlighted the need for improved data collection and quality for measuring current use, along with advocating targeted reduction across the various agricultural sectors. Following this report, the UK government committed to decreasing overall antimicrobial use (AMU) in agriculture to 50 mg/kg by 2018. At that time the AMU data available for the UK was for the 2014 period and sat at 62 mg/kg, meaning a 19% reduction in overall AMU in four years (O'Neill, 2016).

Public interest in the O'Neill report was strong, with much press coverage.

The Chief Veterinary Officer, Nigel Gibbons, wrote that veterinary surgeons had a crucial role to play in efforts to tackle this global issue (Gibbons, 2016). This increasing public awareness of AMR in turn led supermarkets and other sellers of agricultural products to focus their attention on the use of antimicrobials, in particular HP-CIA, by their producers and suppliers. Dairy farmers generally sell their milk either to large milk-buying cooperatives or directly to supermarkets, with some supermarket contracts paying a

premium price, for which farmers must comply with certain additional regulations as set by the buyer. These regulations were initially aimed at improved milk quality; a premium would be paid for milk with low bulk tank somatic cell counts for instance. However more recently it has become increasingly common for milk buyers to stipulate regulations promoting certain antimicrobial use behaviours aimed at improving responsible use. For example, Arla, the largest milk buyer in Europe and the largest dairy company in the UK, introduced a requirement through its farm assurance initiative, Arlagården, in 2015 for its suppliers to use selective dry cow therapy in a certain percentage of the herd when drying off lactating cattle (Arlagården, 2017). That is, a certain number of cattle per year should be dried off at the end of their lactation using only a non-antimicrobial teat sealant. This is in contrast to the historically more commonly used 'blanket' dry cow therapy where all cows that were dried off at the end of their lactation received an antimicrobial intramammary infusion, with or without the use of a teat sealant, in order to treat existing and prevent new bacterial udder infections during the dry period. A recently published study involving a questionnaire of Dutch veterinary surgeons showed that they believed their dairy farmer clients used selective dry cow therapy (Scherpenzeel et al., 2016).

Veterinary surgeons are also under increasing pressure to prescribe antimicrobials more responsibly, with recent guidelines published by the British Veterinary Association (BVA), The British Cattle Veterinary Association (BCVA) and the Responsible Use of Medicines in Agriculture Alliance (RUMA) on responsible prescribing practices (British Veterinary Association, 2015, British Cattle Veterinary Association, 2017, Responsible Use of Medicines in Agriculture Alliance, 2015). In other countries such as the Netherlands, veterinary practices and even individual veterinary surgeons' antimicrobial prescribing practices are being monitored and benchmarked, with interventions occurring at certain

levels of “inappropriate” prescribing. A recent systematic review and meta-analysis has shown a reduction in antimicrobial resistance amongst both animal and human populations where antimicrobial use in agriculture was restricted (Tang et al., 2017).

In the UK veterinary prescribing of antimicrobials is largely unregulated and unmonitored from a ‘responsible prescribing’ point-of-view. Veterinary practices are often private businesses with no umbrella body such as human medicine’s National Health Service (NHS) within which benchmarking could take place. However, the recent change in the demographics of veterinary businesses with a move towards corporatisation has led to some multi-practice initiatives and benchmarking. RUMA have published sector-specific antimicrobial use targets to be achieved by 2020 which include a reduction in HP-CIA injectables and intra-mammary use by 50% and an overall reduction in all AMU of 20% compared with figures for 2015 (Responsible Use of Medicines in Agriculture Alliance, 2017). These pressures on veterinary surgeons to move away from prescribing HP-CIA and reduce overall use of antimicrobials may have variable success depending on the nature of the practice. Those whose business models depend heavily on PVM sales and who feel unable or unwilling to actively reduce use may respond differently to those who see the promotion of health planning, preventive medicine and the reduction of antimicrobial use as an opportunity and a marketing strategy. It has been advocated that veterinary businesses need to move away from a sales-driven business model towards a more preventative healthcare model (Statham and Green, 2015).

Veterinary surgeons are the main source of information about prescribed antimicrobial use for dairy farmers and are therefore pivotal to the agenda of improved responsibility in AMU (Jones et al., 2015). However, veterinary surgeons are perceived to instigate

discussions about animal health only 15% of the time (Hall and Wapenaar, 2012). Veterinary surgeons have several options for communicating information about responsible medicine use to their farming clients; face-to-face contact during herd health planning visits, routine fertility or tuberculosis testing visits, by email or by letter in the form of practice newsletters and via client information evenings and farmer meetings.

In addition to the influence of dairy veterinary surgeons on the use of antimicrobials on dairy farms, farmers are also influenced by industry bodies. For example, the Agriculture and Horticulture Development Board's Dairy division (AHDB Dairy) is a not-for-profit, levy funded organisation working on behalf of the dairy industry. This organisation has a remit which includes funding research specifically aimed at improving the dairy industry and for communicating this research with dairy farmers, along with providing products and services to improve the sustainability of British dairy farming (Agriculture and Horticulture Development Board, 2018). AHDB Dairy have produced many booklets, guides and tools via their website and via agricultural shows, postal mailings and farmer meetings aimed at reducing antimicrobial use and promoting responsible use. Training materials and resources in responsible medicine use have also been made available to farmers by other organisations. The City & Guilds qualification in responsible medicine use, MilkSure training to help farmers avoid medicine residues in milk and the 2018 launch of the National Office of Animal Health's Animal Medicines Best Practice training package are worthy examples (City and Guilds, 2017, British Cattle Veterinary Association, 2018, National Office of Animal Health, 2018a), although involvement in initiatives such as these often require a degree of engagement with the subject and occasionally monetary investment from the farmer.

Dairy farmers therefore have many different sources of information on and drivers for responsible antimicrobial use, however these can vary widely depending on the veterinary practice with which they are registered, the individual veterinary surgeon with responsibility for herd health management decisions on their farm, their milk buyer's farm assurance stipulations and their own awareness of and engagement with the debate through industry bodies, farming and national press, their peers and their own healthcare providers.

2.3 *Prescription Veterinary Medicine Use*

2.3.1 Measuring medicine use

Due to the importance of AMR to the global community, the UK community and specifically the UK agricultural community, the focus of data gathered on veterinary medicine use is usually on antimicrobials. The use of other prescription veterinary medicines such as hormone treatments, non-steroidal anti-inflammatory drugs (NSAIDs) and vaccines has received less attention despite an understanding of the use of these other medicines being extremely important to the AMR debate. Accordingly, there is scant data available for quantifying the veterinary prescription of these other PVM. These other medicines, when combined with management changes, offer potential alternatives to using unnecessary antimicrobials in treating and preventing disease (Responsible Use of Medicines in Agriculture Alliance, 2015).

One of the seven key intervention areas identified in the O'Neill Report was the need to "improve global surveillance of drug resistance and antimicrobial consumption in humans and animals" (O'Neill, 2016, bottom of page 5). Currently in the UK, veterinary antimicrobial consumption is estimated in the Veterinary Antimicrobial Resistance and

Sales Surveillance (VARSS) report, published annually by the VMD (2018c). Historically sales data provided by pharmaceutical companies are converted to a proxy of use by dividing the total sales by a population correction unit (PCU) to provide consumption data in mg/PCU (which they equate to mg/kg in the report) of food producing animals in the UK. Since 2017, the VARSS report has moved toward using veterinary practice sales data to estimate use in the dairy sector (Veterinary Medicines Directorate, 2017, Veterinary Medicines Directorate, 2018c).

The original system of using national level data has advantages – it is relatively straightforward and provides data that conform with EMA requirements and are directly comparable with other EU member states via the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project who also publish reports annually (European Medicines Agency, 2017). It does however also have many limitations. Where a medicine is licensed in more than one species, it can be very difficult to ascribe the mg/PCU correctly to each species. This system also does not account for Cascade or unlicensed medicine use - it lacks granularity and assumes the total weight of antimicrobials sold to veterinary practices reflects the total weight administered to animals. This lack of granularity means that although the data are very useful at an international level for comparing total consumption, it has very limited use for understanding veterinary medicine use within the UK. It is acknowledged that this high-level data does not provide sufficient information to allow more detailed species-specific analysis of use and methods for the collection of data on prescription and administration of antimicrobials in different livestock sectors are under development (Bondt et al., 2013, Borriello and Sharland, 2015).

The 2016 and 2017 VARSS reports (the most recent available at the time of writing) suggest a moving picture, with total antimicrobial sales in all food-producing species decreasing from 57 mg/PCU in 2015 to 45 mg/PCU in 2016 and 37 mg/PCU in 2017, achieving the target set out in the O'Neill report two years early. Sales of HP-CIA also decreased between 2015 and 2017, with fluoroquinolones reducing from 0.34 mg/PCU to 0.16 mg/PCU, and 3rd and 4th generation cephalosporins from 0.17 to 0.12 mg/PCU. The majority of total weight of antimicrobials sold in the UK in 2016 were tetracyclines, beta-lactams and trimethoprim/sulphonamides (Veterinary Medicines Directorate, 2017, Veterinary Medicines Directorate, 2018c).

While estimating species- or sector-specific AMU figures is difficult due to multi-species licensing of some medicines and poor data granularity, the 2016 and 2017 VARSS reports published dairy sector AMU estimates which were based on veterinary sales data for the first time. In 2016 this data was obtained from a single source, with a coverage of 33% of the UK dairy population and over-represented veterinary practices in Northern Ireland while under-representing those in Wales. The report found that there had been an increase in the total weight of intramammary antimicrobials used from 1.64 kg in 2015 to 1.94 kg in 2016. It theorised that this was due to a move away from HP-CIA, with their lower weight of active ingredient per course towards more responsible intramammary antimicrobials which have a higher weight of active ingredient per course (Veterinary Medicines Directorate, 2017).

Public Health England and the VMD produced a joint 'One Health' report on antimicrobial use, sales and resistance which placed the UK as mid-range when compared to other EU countries for both human and animal use, with humans being responsible for 56% of total

antimicrobial use in the UK (Borriello and Sharland, 2015). This report highlights the need for standardised recording and species-level data in the future. A recent UK study aimed to quantitatively evaluate AMU on UK dairy farms through veterinary sales data or farm medicine records gathered from 358 farms for a 12-month period (Hyde et al., 2017). This study found a median AMU of 15.97 mg/PCU (range 0.36-97.79 mg/PCU).

2.3.2 Antimicrobial use metrics

Multiple different metrics for the measurement of antimicrobial use have been developed in human and animal health, with historically little cohesion. Chauvin and colleagues (2001) published a paper making the case for using Animal Defined Daily Doses (ADD) (a variant on the human method of recording use) as the standardised measure of quantifying medicine consumption while comparing it with other measures. Animal Defined Daily Doses or Defined Course Doses were the most common measure of antimicrobial use in the recent literature (Santman-Berends et al., 2014, Ferner et al., 2014, Pardon et al., 2012, Gonzalez Pereyra et al., 2015, Aarestrup et al., 2010, Pol and Ruegg, 2007, Merle et al., 2014, Hyde et al., 2017) however there are many other measures that have been used either alongside or instead of ADD, such as antimicrobial use rate (Saini et al., 2012), absolute weight of ingredient (Ferner et al., 2014), Used Daily Dose (Pardon et al., 2012, Merle et al., 2014) as well as more descriptive data about most commonly used antimicrobials (Sawant et al., 2005, Hill et al., 2009, Zwald et al., 2004).

The methods of recording antimicrobial use on farm also varies between studies, with on-farm records being the most commonly used recording system (Pardon et al., 2012, Menendez Gonzalez et al., 2010, Merle et al., 2012), while veterinary sales data to individual farms (Santman-Berends et al., 2014, Ferner et al., 2014, Merle et al., 2012,

Hyde et al., 2017), farmer recall (Redding et al., 2014) and bin audits (Saini et al., 2012, Redding et al., 2014, Nobrega et al., 2017) are also used. It has been recognised that various factors such as recall bias, non-compliance, incomplete and inaccurate recoding are associated with all methods of recording farm-level medicine use (Zwald et al., 2004, Sawant et al., 2005, Raymond et al., 2006, Pol and Ruegg, 2007, Saini et al., 2012).

The RUMA Targets Taskforce was set up to develop sector specific antimicrobial reduction targets and improve and standardise the measurement of AMU in food-producing animals and published its first report in 2017. In addition to government and industry bodies, private software developers have also seen a market for improved medicine record keeping. This has instigated a wave of new software aimed specifically at dairy farmers and dairy veterinary surgeons with improved PVM recording (ease-of-use, graphics, data analysis, etc.) as a marketed benefit, e.g. VetIMPRESS, Uniform-Agri etc. One of the outcomes of this relatively sudden influx of new approaches to measuring medicine use at the veterinary practice or farm level has been the concurrent development of many different AMU metrics including total mg, mg/kg, daily dose and course dose metrics. A recently published paper comparing different AMU benchmarking metrics in the UK dairy industry concluded that “UK-specific, UK-standardised versions of the daily dose and daily course AMU metrics would bring a balance between data requirements, accuracy to the UK, ease of use and understanding,” thus advocating the development of a new metric specifically tailored to meet the requirements of the UK dairy industry (Mills et al., 2018, bottom of page 8).

In the UK, daily dose metrics are currently in use by major UK retailers, and course doses are being used by veterinary practices and retailers (Mills et al., 2018). Internationally,

there are many metrics used for measuring AMU, with the Netherlands and Denmark both using daily dose metrics tailored for their national situation for measuring and benchmarking purposes (Bos et al., 2015, Statens Serum Institut and National Food Institute, 2018).

The recent paper also highlighted the important point that metrics which measure total number of mg, and reduction targets based upon these metrics “may drive users towards HP-CIAs which often have a lower dose rate and thus make total AMU appear lower for the metrics where total mg is used instead of explicitly accounting for dose or course. Therefore, use of HP-CIAs should be reported separately to total use and it may also be beneficial to have additional targets for HP-CIAs.” (Mills et al., 2018, Page 1)

Given the different legislation surrounding veterinary medicine prescriptions and licensing internationally, it is very difficult to accurately compare the overall use patterns of the UK's POM-V medicines with their equivalents abroad. Prescription veterinary medicine licensing varies between countries and most countries do not publish figures for use of NSAIDs, anthelmintics, vaccines or hormones. It is therefore only plausible to discuss PVM internationally in relation to antimicrobials.

Comparing antimicrobial consumption between countries is a complex and difficult task (Chauvin, 2001). Many countries publish total AMU data in some form, however there is little standardisation of the methodology or metrics for measuring use (Carnevale and Shryock, 2006). In addition to this, farming systems, disease burdens, licensed medicines and livestock breeds make direct comparison unhelpful. A paper by Hillerton and colleagues (2016) compared the official government reports of veterinary AMU of 30

Western countries in 2012. This study placed Norway, Iceland and New Zealand as the lowest users at 3.8, 5.9 and 9.4 mg/PCU respectively. The highest users were Cyprus, Italy and the United States of America (USA) at 396.5, 341.0 and 266.2 mg/PCU respectively. The UK fell mid-table with an AMU of 66.3 mg/PCU. These reports were largely based on national sales data and subject to the same limitations as discussed previously in the UK's surveillance data.

Veterinary sales data has been utilised to estimate AMU in several countries, including the UK (Hyde et al., 2017), the Netherlands (Bos et al., 2015), Denmark (Bondt et al., 2013) and Germany (Merle et al., 2012). Antimicrobial use has been estimated at the farm-level in many countries internationally, including the UK, the Netherlands, Belgium, Denmark, Sweden, Austria, the USA, Canada and Argentina (Hyde et al., 2017, Stevens et al., 2016, Gonzalez Pereyra et al., 2015, Hill et al., 2009, Ortman and Svensson, 2004, Meek et al., 1986, Pol and Ruegg, 2007, Sawant et al., 2005, Santman-Berends et al., 2014). The USA studies have been largely based on questionnaires and surveys utilising recall, whereas other studies have used existing on-farm records or have been longitudinal studies introducing novel record-keeping methods. German, Swiss and Austrian studies have found that veterinary sales data were superior to on-farm record keeping but that both are feasible ways of monitoring use (Merle et al., 2012, Menendez Gonzalez et al., 2010, Ferner et al., 2014). However, a Belgian study found that the most accurate data was obtained from on-farm records due to routine deviation from prescribed dosing (Pardon et al., 2012).

2.4 *Farmer behaviour and decision making*

An understanding of farmer decision making and behaviour is extremely important in order to inform policy and ensure effective interventions when seeking to change behaviour (Garforth, 2015, Escobar and Buller, 2014). A 2017 review of determinants of farmers' adoption of management strategies to prevent or control infectious disease concluded that so called 'socio-psychological factors' are key in instigating behaviour change (Ritter et al., 2017).

2.4.1 Previous literature

Classically, research of farmer behaviour and decision making has been mostly of a quantitative nature, with Likert-type psychometric scales or structured questionnaires forming the majority of the literature on farmer motivations, attitudes and beliefs (Kaupinnen, 2010, Burton, 2004, Willock et al., 1999, Beedell and Rehman, 2000, Dernburg et al., 2007, Richens et al., 2013). The origins of this approach lie in economic models and in health psychology, and although Edwards-Jones argues in his 2006 paper that "traditional economic approaches are most suited for making predictions about decisions which are dominated by financial transactions at a broad scale" (Edwards-Jones, 2006, top of page 784), he and others believed that farmer behaviour is governed by a more complex picture and that emphasis needs to be placed on other influencing factors (Escobar and Buller, 2014, Burton, 2004, Willock et al., 1999). The inherent problems of designing health interventions based on surveys of 'attitudes and beliefs' are discussed in Pool & Geissler's book *Medical Anthropology*, where they state *that* "standardised instruments such as survey questionnaires produce a standard set of decontextualized local beliefs" (Pool and Geissler, 2005, middle of page 37).

Most published studies of farmer behaviour employed Ajzen's Theory of Planned Behaviour (TpB) (Ajzen, 1991), which was developed to improve the Theory of Reasoned Action (TORA) (Fishbein and Ajzen, 1975) as a model for decision making and behaviour (Beedell and Rehman, 2000, Garforth and Rehman, 2006, Garforth et al., 2006, Garforth et al., 2013, Rehman et al., 2007, Rehman et al., 2008, Ritter et al., 2017). However, it has been suggested that agricultural research using the TpB has focussed too much on attitudes, without due consideration for other important 'external' factors such as 'subjective norm' and 'perceived behavioural control' (Escobar and Buller, 2014, Burton, 2004, Burton et al., 2012). The Theory of Planned Behaviour frames behaviour as an outcome that can be determined in advance by an individual's internal mind-map (Escobar and Buller, 2014) although Ajzen himself concedes that predicting intentions does not necessarily predict actual behaviour due to other (external) factors (Ajzen, 2015).

Another approach commonly used was that of the Health Belief Model, developed by social psychologists as a research and intervention tool (Janz and Becker, 1984). In essence, it assumes that people's beliefs determine their behaviour in a direct and rational fashion and by understanding beliefs we can understand and change behaviour. Anthropologists argue that this is simplistic and flawed. Beliefs are relative and context dependent, and they do not drive behaviour in any direct way but are subject to structural constraints (Pool and Geissler, 2005).

Gasson's seminal paper identified four sets of values that underpin farmer behaviour and motivation (1973). These values were 'instrumental' (those concerned with financial and business goals), 'social' (relating to prestige and tradition), 'expressive' (creative values and self-expression) and 'intrinsic' (the independence and enjoyment of farming). A 2008

study identified five different types of behavioural motivation as 'family orientation', 'business/entrepreneur', 'life-stylers', 'enthusiast/hobbyist' and 'independent/small farmers' (Rehman et al., 2008). This model was further refined in the Department for the Environment, Fisheries and Rural Affairs (DEFRA)'s 'segmentation model' which categorised and estimated the proportion of farmers in each section as follows: 'modern family business' (41%) which are focussed on making a profit and ensuring the future of the enterprise, 'custodians' (23%) who are influenced by environmental and heritage factors, 'pragmatists' (22%) that wish to balance a viable business with a love of farming, 'life-style choice' (6%) who are more motivated by farming than making money and usually have other sources of income, and 'challenged enterprise' (7%) which are struggling and pessimistic about the future survival of the business (Pike, 2008). Quantitative approaches to understanding decision-making and predicting behaviours such as the Edinburgh Study of Decision Making on Farms (Willock et al., 1999) have aimed to create multivariable models using Likert-type scales to model attitudes, objectives and behaviours although these models have not been widely used since.

Segmentation theory has been very popular for many years, however in a recent report to DEFRA, Escobar and Buller reason that although quantitative analysis based on these farmer segmentation models tend to be favoured by policy makers, more emphasis should be placed on other methodologies such as ethnographies, biographical and narrative approaches and in-depth interviews (amongst others) in order to provide a richer and more detailed picture of farmer behaviour (Escobar and Buller, 2014). Additionally, in-depth interviews of farm workers, share-milkers and farm owners in New Zealand led Burton and colleagues to propose that farmer behaviour be reconceptualised as part of a self-reinforcing culture in which animals, humans and the physical

environment all contribute to farm-specific behaviours (2012). This 'cultural turn' from behavioural approaches using quantitative research methodology to qualitative methodology in agricultural science has been lagging behind when compared to other behavioural sciences (Burton, 2004).

2.4.2 Medicine-specific behaviour

Values, perceptions and behaviours surrounding the use of veterinary medicines by farmers is an area with an overwhelming need for further research (Buller et al., 2015). It has been shown that farmers regularly exceed datasheet guidelines for treatment duration of clinical mastitis because they feel insecure about how to treat mastitis effectively (Swinkels et al., 2015), and Belgian and Austrian studies have shown both overdosing and underdosing of medications to be common in pigs (Timmerman et al., 2006, Trauffler et al., 2014). It is therefore likely that other veterinary prescription medicines are not used according to datasheet guidelines on farms, despite this assumption being made in all current estimates of use. Similarly, it has been shown in human medicine that a variety of social and cultural influences and beliefs can affect compliance when prescribing medicines (Martin, 2005). Understanding the reasons why this may be the case requires a qualitative methodology in order to investigate this phenomenon further and to inform future policy interventions.

Social norms also play a key role in medicine-use behaviours. It has been said that "every medicine is given particular, often varying and changing, meanings in any given context, producing a multiplicity of ideas and practices" (Pool and Geissler, 2005, top of page 89). Swinkels and colleagues explored the social influences on the duration of antimicrobial treatment in mastitis and found that extending treatment duration had become the social

norm (2015). A study of small animal veterinary surgeons in the UK also found social norms influenced prescribing behaviour, particularly verbally agreed protocols (Mateus et al., 2014). Client pressure was identified in the UK, the Netherlands and Ireland as playing a role in veterinary surgeons' antimicrobial prescribing (Coyne et al., 2014, Gibbons et al., 2013, Speksnijder et al., 2015). A recent UK questionnaire-based study linked increasing frequency of veterinary contact with more responsible antimicrobial use and greater knowledge of AMR (Higham et al., 2018).

A study analysing the UK press' coverage of agricultural antimicrobial use and AMR in recent years (Morris et al., 2016) showed a clear disagreement between relevant actors. Groups such as the Soil Association and Alliance to Save our Antibiotics framed the issue as system failure, while policy makers, regulatory bodies and farmers believed there was little evidence about the contribution of agricultural use to the growing problem of AMR. In the farming press, voluntary action in order to protect the public image emerged as a theme. The study advocated strongly for the use of ethnographic and interview-based techniques in order to research actual use of antimicrobials on-farm.

Of the small body of qualitative literature on PVM use not based on health-psychology approaches, the use of semi-structured in-depth interviews has been the most common research method. A Danish study interviewed 16 dairy farmers to identify factors involved in mastitis treatment and found that decisions were made on three levels: the symptom level, the cow level and the herd level (Vaarst et al., 2002). A Norwegian study explored farmers' use of homeopathy through interviews, with personal experience proving important and decisions made both at the cow and the herd level (Hektoen, 2004). A study of UK dairy farmers' motivations for vaccination use found the veterinary surgeon

played an important role in decision making in the implementation of vaccination strategies (Richens et al., 2015).

2.5 *Human medicine use*

One of the most common health care interventions in the UK is the prescribing of medicines in primary care, and over 1.1 billion items were prescribed and dispensed by the NHS in 2016 (National Health Service, 2017). Given that these prescriptions occur under the umbrella of the NHS and given the greater scale, impact and funding available within human medicine it is unsurprising that there is a far larger body of literature about medicine use behaviours and prescribing decisions in this area. Reviewing some of the key elements of this literature can provide an insight into factors that may be of equal importance if applied to veterinary medicine use in the farm context.

2.5.1 Measuring use

Within NHS Primary Care in England, prescription data from general practitioners is gathered continuously with analysis of trends in medicine use being used for benchmarking, feedback and policy interventions (National Health Service, 2018). Data on prescriptions dispensed in the community are published annually (National Health Service, 2017) and Clinical Commissioning Group (CCG) prescribing, practice-level prescribing and Primary Care Trust prescribing data are all made publicly available. The availability of core information technology (IT) systems, combined with the centralised reimbursement of pharmacies for prescriptions dispensed provides a standardised and valid source of data on medicines dispensed into the community from general practitioners although may fail to capture some medicines prescribed by out-of-hours services and those prescribed by dentists. Traditionally, prescribing has been measured

using the number of items prescribed and the associated costs. Patient population data can be drawn from patient lists and allows the publication of data on items per patient, cost per patient and cost per item. In addition to these statistics, other measures have also been developed, including measures of volume, Defined Daily Doses (DDDs), Average Daily Quantities (ADQs) and patient denominators (Jones et al., 2004).

While measuring medicine prescribing and dispensing is relatively simpler in human medicine than in veterinary medicine in the UK for the reasons outlined above, measuring actual medicine use (i.e. the medicines actually taken by the patient) in the human population in primary care is an equally complex issue to measuring use in veterinary medicine. Self-report questionnaires - while common and simple to implement - have not been validated or standardised and are open to the fallacy of memory (Lafleur and Oderda, 2004).

2.5.2 Decision making and medicine use behaviours

There is a large body of evidence showing that prescribing decisions and medicine use behaviours in human health are influenced by many factors (Public Health England and Department of Health, 2015). The majority of the published research relates specifically to the prescription and use of antimicrobials which is unsurprising given the relative importance of understanding and reducing antimicrobial prescribing compared with other medicines. Given the link between antimicrobial prescribing and resistance has been made (Costelloe et al., 2010), one focus now is on qualitative research in order to better understand the root causes of antimicrobial use.

Social norms were identified as having a significant effect on prescribing. Clinicians' prescribing in hospitals was influenced by the perceived prescribing norms and

encompasses risk-aversion and hierarchical structures (Broom et al., 2014, Lewis and Tully, 2009). Parents' and clinicians' expectations and decisions about antimicrobial use in children were influenced by the subjective norms of perceived child vulnerability and the clinicians' role in ensuring child safety (Cabral et al., 2015).

Uncertainty was identified as a strong driver of prescribing behaviour. Uncertainty and diagnostic complexity could lead to unnecessary prescribing of antimicrobials in cases of acute cough in adults and respiratory tract infections in children (Lucas et al., 2015, Whaley et al., 2013). Prescriber anxiety about the consequences of not prescribing (i.e. risk averse behaviour) was a dominant theme highlighted by the Department of Health's literature review of antibiotic prescribing in primary care (Public Health England and Department of Health, 2015). As such, antibiotics were used to mitigate uncertainty. Inappropriate prescribing can therefore, in turn, reinforce health-seeking behaviour whereby a patient feels validated in seeking treatment and will subsequently be more likely to seek similar treatment.

Lived experience is important and it has been shown that if a similar illness resolved with antimicrobial treatment in the past, there was a greater expectation of future antimicrobial treatment (Ingram et al., 2013). Perceived patient expectation of antimicrobial prescribing influences prescribing behaviour. Clinicians prescribe when they feel pressured to do so, when they feel there is a clear indication and also when they feel uncertain, "just in case" (Lucas et al., 2015, Whaley et al., 2013). Clinicians avoid prescribing when concerned about side effects or resistance, when they are certain antimicrobials are not needed or when there was no pressure to prescribe (Lucas et al., 2015). However, it has also been shown that clinicians are not particularly adept at

identifying when patients do expect antibiotic treatment (Mangione-Smith et al., 1999). A study by Little and colleagues in 2004 showed that clinicians' decisions were more strongly associated with perceived medical need, and this effect confounded all others. However perceived patient pressure was a strong independent predictor of clinicians' behaviours in relation to investigations, be they referral or prescribing (Little et al., 2004).

More generally, there has been work looking at the use of medicines other than antimicrobials in human health. It has been shown that side effects can influence use as well as convenience, ease-of-use and availability. Non-adherence to prescribed use can be caused by 'medicine burden' where prescription of several medicines leads to a feeling of burden (Katusiime et al., 2016). Conversely, satisfaction with treatment and medicines is positively associated with medicine use (Barbosa et al., 2012).

"There is a recognised need for health systems to understand and monitor patients' experiences (of medicine use), to improve quality of care." (Katusiime et al., 2016, bottom of page 158).

This philosophy can be applied equally to the care of farmed animals and the need to understand and monitor farmers' experiences of medicine use to improve the health and welfare of the animals under their care.

2.6 Knowledge Gaps

It is clear from the review of literature surrounding veterinary medicine use on UK dairy farms that there remain many areas requiring investigation. Several knowledge gaps have been identified, and some of them form the basis for this thesis:

Need for data on prescription medicine storage practices. Very little is currently known about the way medicines are stored on UK dairy farms and farmers are assumed to be storing and disposing of medicines appropriately by policy makers, academics and veterinary surgeons.

Lack of granularity of data. While measuring veterinary medicine use in the UK is improving in granularity with a move from national-level data collection towards veterinary practice level data, data at the farm and individual cow level on medicine use is lacking despite the requirement that farmers keep detailed medicine records for each individual animal. There is no currently published research seeking to validate veterinary practice sales data or on-farm medicine records and therefore, even with a move towards granularity, it is currently unknown how well these data reflect actual use.

Need for data on non-antimicrobial PVM use. The lack of literature on quantifying the use of NSAIDs, vaccines, hormones and other PVM in UK dairy cattle despite their importance in a holistic approach to herd health management and responsible medicine use suggests this is an area with an urgent need for research.

Need for ethnographic study of medicine use behaviours. While measuring medicine use provides vital information for benchmarking purposes, design and implementation of policy interventions requires an understanding of the reasons for medicine use behaviours and decisions by farmers. This has been identified as an area with an “overwhelming need for further research” as previously mentioned (Buller et al., 2015, middle of page 65). Additionally, the context and culture within which medicine treatment decisions are being made on farms has not been previously investigated.

These identified knowledge gaps justify the aims of this thesis and the research paradigms from which the methodologies used were drawn. Due to the lack of available data with which to form a hypothesis for testing, this thesis is largely theory-generating and exploratory and, as such, focusses on achieving rich in-depth data, based on a small number of farms rather than providing a representative sample from which conclusions can be drawn and inferred upon the entire population.

Chapter 3 Methodology and Methods

3.1 *Abstract*

It has been suggested that mixed methods and interdisciplinary approaches are best suited to answer complex questions as they have an ability to be tailored for the needs of the research questions (Pope and Mays, 2006). It is important when designing, implementing and analysing rigorous scientific research that the researcher is aware of the research paradigm within which (s)he is working. A research paradigm is defined as “the set of common beliefs and agreements shared between scientists about how problems should be understood and addressed” (Kuhn, 1962, top of page 44). Once the methodology and research paradigm have been defined, it is then possible to design and prescribe the specific research methods with which to investigate the research questions. This chapter presents the ontology and epistemology of the thesis, explores the strengths and potential limitations of mixed-methods research and the research methodologies utilised, sets out the theoretical framework and finally describes the research methods employed to investigate the research questions laid out in Chapter 2.

3.2 *Ontology and epistemology*

A research paradigm can be broken down into the ontology and epistemology of the researcher.

The ontology refers to the researcher's view on the nature of reality, and, in its most basic form, ranges from **realism** (there is one reality, and everyone experiences it in the same way) to **relativism** (there is one reality, but there are many different ways of experiencing it) to **solipsism** (there is no reality, it is merely a product of the mind). The epistemology refers to how the researcher believes that reality can be known (Wahyuni, 2012).

Epistemology can be broadly divided into three main groups:

Positivism - There is a single reality which can be measured and known. Positivism is most likely to result in quantitative research methodologies.

Constructivism/Interpretivism - There is no single reality or truth, and therefore reality needs to be constructed and interpreted. Researchers with a constructivist/interpretivist epistemology are more likely to use qualitative methods to capture those multiple realities.

Pragmatism - Reality is constantly renegotiated, debated and interpreted, and therefore the best method to use is the one that solves the problem. Mixed methods research is often pragmatic in epistemology (Pope and Mays, 2006).

Due to the complexity of the research questions at hand, this thesis aligns most readily with a pragmatist epistemology and, as such, uses a mixed methods design.

The measurement of actual PVM use on UK dairy farms and the comparison of veterinary sales data with on-farm medicine records and medicine use as recorded by medicine waste bins is positivistic in nature as it assumes that there is one knowable truth – there is one correct figure for medicine use and measures for that figure can be contrasted with the hypothesised truth. This is realist in ontology. However, this thesis also aims to understand the beliefs and values of dairy farmers, and the context and culture within which PVM use behaviours occur. The ontology of this enquiry is more relativist and is interpretivist in epistemology - it seeks to interpret the social construction of reality in order to provide insight and explanation for decision-making behaviour. Therefore, taken as a whole, this thesis is written from a pragmatic epistemology, where research methodology was chosen depending on the specific research questions.

3.3 *Mixed methods research*

Mixed methods research has been defined as “Research where the researcher mixes or combines quantitative and qualitative research techniques, methods, approaches, concepts or language into a single study” (Johnson and Onwuegbuzie, 2004, bottom of page 17). Its use is increasingly popular in healthcare research (Tashakkori and Teddlie, 2010, O’Cathain et al., 2013) although in some fields it remains controversial due to a belief in the principle that methods should not be mixed (Howe, 1988).

Quantitative research paradigms emphasise objectivity, measurement, standardisation and minimising bias, whereas qualitative paradigms focus on understanding, flexibility, insight, subjectivity and are highly reflexive. This can, by definition, make mixed methods research a dichotomy that is difficult to reconcile, however its use is driven by pragmatism rather than principle and is motivated by a perceived deficit of either quantitative or

qualitative methods alone to address complexity in health care research (O'Cathain et al., 2007). In this sense, mixed methods research can counterbalance and complement the strengths and limitations of both qualitative and quantitative research; these methods can address complexity and can help to reduce the knowledge-practice gap, enhancing the impact and usefulness of scientific research (Bryman, 2006).

The identified knowledge gaps that prefaced the development of the research questions at the heart of this thesis naturally lend themselves to mixed methods research. Understanding veterinary medicine use on UK dairy farms cannot be achieved through one research methodology alone and is inherently complex. Through a mixed methods approach, the research questions can be answered in different ways, with integration and triangulation of data analysis providing robust and valid answers. Qualitative research findings can help with interpretation and explanation of quantitative data and vice versa, leading to a sum greater than its parts and providing “additional perspectives and insights that are beyond the scope of any single technique” (Borkan, 2014, top of page 4). As summed up by Mason in 2006, “Mixing methods...offers enormous potential for exploring new dimensions of experience... and intersections between these. It can encourage researchers to see differently, or to think ‘outside the box’, if they are willing to approach research problems with an innovative and creative palette of methods of data generation” (Mason, 2006, top of page 10).

3.3.1 Methodological Triangulation and Pluralism

Pluralism (or methodological triangulation) is the ultimate purpose of mixed methods research. While investigating a problem using different methods is useful, its power lies in the triangulation of these different techniques and in their combined interpretation.

Pluralism can therefore enable a rich and comprehensive picture of the research question (Foss and Ellefsen, 2002) and increase the robustness and validity of any single dataset by seeking to compare and contrast it with other methodological ways of answering complex questions (May et al., 2017). In essence pluralism is asking whether the results make sense given the wider context, and it has been argued that in using data from opposing epistemological backgrounds it is possible to “explore different, sometimes even contradictory, layers of meanings of realities”(Hoque et al., 2013, middle of page 1173).

3.3.2 Quantifying medicine use

The two most common ways that researchers have used to quantify veterinary medicine use on farms have been through use of veterinary practice sales data and on-farm medicine records. Most studies have retrospectively measured these data; (Davies et al., 2017, Hyde et al., 2017, Hill et al., 2009, Gonzalez Pereyra et al., 2015, Pol and Ruegg, 2007, Zwald et al., 2004, Ferner et al., 2014, Merle et al., 2012, Bondt et al., 2013) however, some have provided new recording systems (medicine waste bins, computer or smartphone software, medicine record sheets) and prospectively and longitudinally measured use (Stevens et al., 2016, Ortman and Svensson, 2004, Menendez Gonzalez et al., 2010). This thesis aimed to compare veterinary sales data with on-farm medicine records and medicine waste bins in order to measure the agreement between different recording methods and to determine the relative strengths and limitations of each technique compared with a defined “gold standard”.

3.3.2.1 *Veterinary sales data*

Veterinary sales data is currently seen as the data of choice to measure veterinary medicine use by researchers, government bodies and veterinary practices (Veterinary Medicines Directorate, 2018c). This is due to the relative ease of obtaining data from

practice management software, the fact that these data should already exist for every farm in the UK, and the perception that the data is likely to be reasonably valid. This validity is assumed because prescription veterinary medicines are recorded every time they are dispensed to a farm and it is in the interests of veterinary practices (which in the UK are private businesses) to accurately record medicine sales in order to correctly charge for them.

The use of veterinary practice sales data has potential limitations. Many farms are mixed-species enterprises and medicine sales are not always accurately ascribed to the correct species. Additionally, veterinary sales data over any given time-frame does not necessarily equate to veterinary medicine use and does not account for medicines bought and stored on farm for use at a later date. This time-lag between purchase and use of veterinary medicines means it is difficult to know whether a medicine was used or stored during the time-period being studied. Veterinary medicine sales data also fail to capture medicines which are discarded or wasted, either through human error (dropped/broken/lost medicines) or medicines discarded due to contamination or expiry.

Another potential drawback of veterinary sales data as a measure of medicine use is the acquisition of PVM by other means. Farmers are able to use online pharmacies in order to purchase PVM. These pharmacies require a written prescription before being legally allowed to dispense PVM, but these prescriptions may not be captured within the sales data obtained from veterinary practices. Most anthelmintics and many vaccines licensed for use in UK cattle (13 out of a total of 55) are classed as POM-VPS and as such can be acquired through an SQP from veterinary practices or other outlets and therefore their sale will not necessarily be captured (Veterinary Medicines Directorate, 2018b). There is

also the possibility for administrative error when inputting veterinary sales into practice management software, and errors by a factor of ten or one hundred have been reported anecdotally by the farmer participants in historical veterinary invoices. While it is likely that these errors will be noticed and corrected by the farmer upon receiving the invoice if the error overestimates the actual sale and therefore overcharges, where errors underestimating the volumes sold are present these may be more likely to be unreported and unresolved. In addition to this, there is anecdotal evidence of illegal purchase and/or import of PVM to dairy farms in the UK (British Broadcasting Corporation, 2005, Vet Times, 2018). Where this has occurred, veterinary sales data will not represent all PVM acquired by a farm.

3.3.2.2 *Medicine records*

As previously described, all dairy farms in the UK are required to keep veterinary medicine treatment records including details of the animal treated, the drug, treatment date and quantity. In theory, therefore, these records should provide superior data for actual use of veterinary medicine in dairy farming as they are not subject to the limitations of veterinary sales data (discussed above) and provide greater granularity and detail. However, it has been established that farmers do not prioritise medicine record keeping (Escobar, 2016). The various other time pressures of dairy farming along with a perceived lack of value of these records can lead to medicine records being completed retrospectively and solely to meet the requirements of farm assurance without accurately reflecting actual use.

Given the retrospective nature of record keeping on many farms, in practice on-farm veterinary medicine records come with many limitations. The possible recall bias and

reliance on memory - of the medicines used, the volumes, and the animals' identities - are likely to reduce the quality and accuracy of the records progressively with the passage of time. Farms where records are completed at the time of treatment are likely to be most accurate. Farms where records are completed daily may still correlate well with actual use; however, on farms where medicine records are completed weekly, monthly or even annually before a farm assurance inspection they are unlikely to accurately reflect use on farm. Given that farmers have an awareness that farm assurance cannot determine between accurate veterinary medicine records and fabricated veterinary medicine records, there is likely to be little motivation to maintain up-to-date and accurate records. On-farm medicine records can be kept in many different forms, with computerised records and paper-based records both common (Escobar, 2015).

3.3.2.3 *Medicine waste bins*

The use of medicine waste bins to record medicine use is relatively novel, with a Canadian mastitis treatment study using waste bins to record all mastitis treatments across 89 dairy farms for twenty months (Saini et al., 2012). This study, however, did not compare medicine waste bin data with on-farm records or veterinary sales data. A related publication compared the quantification of antimicrobial use across 51 Canadian dairy herds using treatment records or medicine waste bins and found bins to be superior; treatment records underestimated use significantly (by >50% across all participating herds) but were positively correlated with medicine bin inventories (Nobrega et al., 2017). A recent study investigating the use of veterinary medicines on 20 Peruvian farms used waste bins as a proxy for medicine records because farms did not routinely keep records of veterinary treatment (Redding et al., 2014). This study found that bins were more accurate than self-reporting for bottles of antibiotic, but self-report was superior when

measuring intramammary tubes. It also found that there was very little agreement between the two methods.

Veterinary medicine waste bins aim to improve the measurement of medicine use data from veterinary sales data by being more time-sensitive and accounting for wasted and discarded medicine. They also aim to mitigate against the limitations of farm medicine records by not relying on memory and being simple and easy for farmers to use. The use of medicine bins does, however, ask farmers to alter their behaviour from disposing of veterinary medicines either in normal waste or in clinical waste bins. Hence, this method of data collection is subject to a reliance on farmers to remember to dispose of the medicines in the correct bins.

For this study, medicine bins were chosen as a third measuring tool in order to quantify the difference in the three most common methods of medicine recording (veterinary prescription records, on-farm medicine records and medicine waste bins), and to compare them to a 'gold standard' for actual medicine use as defined in Chapter 5. When used in terms of method agreement analysis, the term 'gold standard' does not in fact refer to a perfect measure by which all others can be compared. That is known as the 'ground truth'. Instead, "a gold standard in its true meaning, derived from the monetary gold standard, merely denotes the best tool available at that time to compare different measures" (Claasen, 2005, middle of page 1121).

3.3.3 Qualitative research

Qualitative research "is a form of social enquiry that focuses on the way people interpret and make sense of their experiences and the world in which they live" (Holloway, 1997, middle of page 54). Qualitative research is also an umbrella term for many different

research methodologies and paradigms, including psychology, sociology, anthropology and geography.

The field of veterinary science has long relied on quantitative research methods in order to answer the “what, when and where” questions pertaining to the profession. However, when it comes to investigating why and how people behave the way they do, many questions are best answered using a qualitative approach (Richens et al., 2013, Christley and Perkins, 2010) as this approach can “reach the parts that other methods cannot reach” (Pope and Mays, 2006, page 22). In human medicine, qualitative research methods have been used for many years to investigate motivation, uptake of advice, risk behaviours and other social aspects of human health (Green, 1998) and there is a research journal, *Social Science in Medicine*, dedicated to its use in human healthcare. Medical sociology and medical anthropology are important scientific fields in their own right, providing invaluable insights into the beliefs, values, behaviours and contexts within which health decisions and practices are conducted. It has become accepted within the human medical field that design of any clinical trial or health intervention will also include investigation of sociological aspects and that qualitative techniques will inform the design of quantitative research (Pope and Mays, 2006).

Historically, qualitative research has not been a popular methodology amongst veterinary researchers, with veterinary peer-reviewed journals consisting almost exclusively of quantitative research until recent years. While other scientific fields such as those of rural studies and rural geography have long studied farming through qualitative methods, these research findings very rarely filter into the veterinary community and are published in journals that have little direct impact on veterinary practice.

Although qualitative methods have not been popular amongst veterinary researchers in the past, a paradigm shift appears to be occurring and these methods are beginning to make their way into the veterinary consciousness. For example, ethnographies and participant observation have been used in order to investigate the local differences in application of tuberculosis testing protocols between veterinary practices, arguing against a 'one-size-fits-all' approach (Enticott, 2012). Qualitative in-depth interviews have been used to investigate perceptions and practices of farm record keeping and have shown a distinct difference between what regulators believe records are used for and how farmers use them (Escobar, 2015). In-depth interviews have also been used in a study of how farmers perceive the veterinarian's role in vaccination strategies on dairy farms and show an opposing viewpoint between veterinarians and farmers (Richens et al., 2015) amongst many other studies as discussed in Chapter 6. It is therefore clear that these methodological approaches can answer some questions that quantitative methods cannot, particularly in identifying cultural and social differences between values, perceptions and behaviours.

3.3.4 Ethnography

Ethnography is both a methodology and a theoretical framework. As a research methodology, ethnography has been used by geographers to explore rural contexts and by medical anthropologists to investigate human health behaviours. As a theoretical framework, ethnography seeks to learn about people, not to study them, through immersion in the population of interest (Jones, 2017). It has traditionally been associated with prolonged periods of immersive participant observation, although it in fact describes data collection through a wide range of different methods. Ethnography is not, however, another word for qualitative research. The use of semi-structured in-depth interviews,

questionnaires, discourse analysis, informal interviews and quantitative data can all contribute to an ethnography, although it is still generally accepted that a significant amount of data should be gathered through participant observation in order to contextualise and validate the other data sources (Savage, 2000).

Savage (2000) argues in the *British Medical Journal* that modern ethnography can be defined as “any small-scale social research that is carried out in everyday settings, uses several methods; evolves in design throughout the study; and focuses on the meanings of individuals’ actions and explanations, rather than their quantification.” Ethnography as a methodology is recognised as being difficult to define. In O’Reilly’s book “*Ethnographic Methods*” (2012), she argues for the definition of ethnography as a methodology informed by a theory of social life as practice. Hammersley and Atkinson (2007, middle of page 3) describe it thus: “Ethnography usually involves the ethnographer participating ... in people’s daily lives for an extended period of time, watching what happens, listening to what is said, and/or asking questions through informal and formal interviews.... In fact, gathering whatever data are available to throw light on the issues that are the emerging focus of inquiry”.

Within the fields of veterinary medicine and agriculture, the use of ethnographic methodologies has been relatively limited and mostly confined to the disciplines of rural geography, education or epidemiological fieldwork in low and middle-income countries (Mariner and Paskin, 2000). Examples of some of these ethnographic studies include work by Enticott (2012), who has used an ethnographic approach when investigating the relationship between bovine tuberculosis, government disease surveillance, biosecurity, veterinarians and farmers in endemic areas. Other work has sought to understand the

effect of robotic milking technologies upon on-farm culture (Holloway et al., 2014), the culture within a veterinary hospital (Atwood-Harvey, 2003), and a 'focused ethnography' to study veterinarian decision-making around diagnostic sampling in Alberta, although this consisted of only a small number of in-depth interviews (Sawford et al., 2013). Patricia Morris' (2012) book "Blue Juice: Euthanasia in veterinary medicine" was the product of her ethnographic research over 18 months in numerous North American veterinary establishments and examines how veterinarians "deal with the responsibility of ending their patients' lives". This selection illustrates the broad applicability of ethnography as applied to veterinary medicine and animal health and highlights the potential for much greater use of the methodology in this field.

In human medicine, ethnographies have the potential to be impactful on medical practice and are seen as providing valuable evidence on which to base policy decisions and health interventions, although it has been argued that their use is overlooked (Savage, 2000, Goodson and Vassar, 2011, Jones, 2017). Medical anthropologists commonly use ethnographic methodologies to explore health behaviours, contexts and cultures (Savage, 2000). These have included autoethnographies describing the experience of being a patient (Greenhalgh, 2017), ethnographies investigating causes of intravenous medication errors (Taxis, 2003), nursing older patients (Costello, 2001) and the seminal medical anthropology work "Boys in white: student culture in medical school" by Becker and colleagues (1961). While there are numerous other examples of the methodology's usefulness to human healthcare, when viewing this selection through the lens of veterinary medicine it again highlights how ethnography could be used more widely to address under-researched areas of veterinary work.

3.3.4.1 *Semi-structured in-depth interviews*

One of the most commonly used research methods in qualitative research is the semi-structured in-depth interview. In contrast to structured interviews and questionnaires where pre-specified questions are asked in a pre-determined order (often with Likert-Scale type response options), semi-structured in-depth interviews follow a loose structure using open-ended questions. These 'guided conversations' combine structure with flexibility, allowing the interview to be interactive and generative. These interviews should be conducted face-to-face in order to maximise their value, and they explore the area of research interest in rich depth, often lasting around an hour (Whiting, 2008). Their ultimate aim is to investigate the experiences and perspectives of an individual of interest on a chosen subject (Dicicco-Bloom and Crabtree, 2006). The flexibility of this method allows the interviewer to adapt the questioning and interview focus and to probe areas of interest depending on the interviewee's responses.

Semi-structured in-depth interviews aim to obtain vivid accounts of the interviewee's experiences and narratives, to gain insights into the interviewee's perspectives on a topic and to explore areas that may not have been foreseen by the interviewer when preparing for the interview. In order to maintain some focus and consistency between interviews, a topic guide is created containing a loose framework for the topics which the interviewer wishes to cover. These topic guides are mainly used as an aide-memoire to avoid neglecting to ask about specific areas of interest, however their use is inductive, and the topic guides can change and develop as more interviews are conducted.

Interview questions are open-ended in order to allow the participant to express their perspectives and thoughts without imposing a framework or agenda, according to what

they feel is important. Questions can be broadly categorised into content-mapping questions and content-mining questions. Content-mapping questions seek to identify the issues relevant and important to the participant, through encouraging a narrative, focussing more narrowly on the areas of interest and prompting the participant to consider other issues. Content-mining questions aim to explore the meaning and gain an in-depth understanding of the participant's responses through further probing by seeking clarification, amplification or explanation.

In veterinary research, the use of semi-structured in-depth interviews has increased in recent years, with Richens (2013) undertaking a rapid-evidence review on the methods used to collect farmers' attitudes towards cattle production which showed that while the majority of studies used questionnaires, over a third of studies used interviews to collect data.

Semi-structured in-depth interviews must be conducted and analysed reflexively, with a tacit understanding that simply by asking the question the researcher is affecting the responses. Participants may respond based on what they believe is the "correct" answer, or the answer expected of them. Interview situations are by their nature artificial and this can influence responses. Interviews are best conducted face-to-face in order to establish a rapport, build empathy and enable non-verbal communication and cues to be seen. An interviewer must avoid using leading or loaded questions and allow the participant to express him-/herself without fear of judgement. By summarising a participant's response and reflecting it back, the interviewer can allow the participant to validate his/her response and the interviewer's understanding. When conducted correctly and analysed in light of the limitations and pitfalls of interviewing, semi-structured in-depth interviews

have been acknowledged to provide valuable, robust and valid data (Whiting, 2008). Qualitative interviews are often a rewarding experience for both the interviewer and the participant. Liamputtong and Ezzy (2005, page 214) report that “in-depth interviewing is a privilege...we often find it surprising and humbling that people are prepared to share so much of their lives with someone”.

3.3.4.2 Participant observation

Participant observation is the cornerstone of modern social anthropology. Its origins lie with Malinowski who conducted fieldwork on the Trobriand Islands between 1915-1918 and it was refined in the 1920s and 1930s by the Chicago School of Urban Sociology (Malinowski, 1922). The characteristic of participant observation is the focus on the context, where the researcher becomes a part of the social world being studied.

Participant observers immerse themselves for prolonged periods of time within the social environment which they wish to study. This is generally informal, overt and involves active participation in activities and the development of relationships with the observed participants. Observational data is collected through the maintaining of ethnographic fieldnotes. Participant observation aims to collect valid observational data, to understand a context and culture through embodied experience, to understand participant's viewpoints and to enable the researcher to directly compare what people say with what they do. “A good way to learn about any of these worlds is to submit oneself to the daily round of petty contingencies to which they are subject” (Goffman, 1961, ix-x). Participant observation can be used to help identify distinctions between participants' and “outsiders'” perspectives. It can explore the meanings people attach to events, actions and decisions.

Ethnographic fieldwork can be time-consuming and difficult to focus due to the extensive nature of the research and the large volume of data that is collected. It is important to narrow the research questions inductively and iteratively throughout the duration of the fieldwork in order to focus down onto the real areas of interest. Data can be collected from the environment, from objects, from social interactions as well as from documents, images and photographs.

Ethnographic fieldnotes involve a different kind of writing (Emerson et al., 2011) where first impressions are noted, and an attempt is made to 'make the familiar strange' (i.e. describing something as if seeing it for the first time, without preconceptions). Initial notes are taken by the researcher while in the field and contain key events, quotes and impressions. These are written in shorthand initially, and then written up as fieldnotes within a limited period of time so as not to lose any valuable information. These fieldnotes typically focus on context, timelines, the people present, their roles and relationships with each other, what is said and what is done. They distinguish between observed events and the researcher's impressions of events, which are often kept in a separate research diary (Pope and Mays, 2006).

The presence of the researcher can have a modulating effect on the behaviour of the observed participants (the so-called 'Hawthorne effect'), although this effect appears to reduce over time and is one of the reasons why prolonged fieldwork is necessary in participant observation (Holden and Bower, 1998). It is important to be reflexive in observational studies, and the positioning of the researcher and their characteristics (for example whether the researcher is male or female, young or old) must be considered as these characteristics will influence the data collection. The researcher needs to gain

access to, and become accepted by, the participants. They must, however, avoid 'going native': a scenario where the researcher becomes so immersed in the researched world that they are no longer able to objectively analyse the setting (Pope and Mays, 2006).

3.4 *Theoretical framework*

The theoretical framework and perspective of this thesis must be understood in order to appreciate the research methodologies used and the subsequent analysis of these data. As previously discussed, ethnography is a term that can be used to refer to a research methodology or a theoretical framework. Here the other contributing theories and methods that comprise the theoretical framework utilised in this thesis will be discussed; grounded theory, thematic analysis and the data analysis software itself.

3.4.1 Grounded Theory

Glaser and Strauss (1999) introduced grounded theory in order to describe the inductive way in which coded qualitative data could be analysed by identifying themes that 'emerged from the data'. A pivotal feature of grounded theory is that it is cyclical and inductive, with each stage informing the next. Therefore, the initial data informs the further collection of data and allows for testing of emerging theories. This theoretical sampling allows the researcher to select participants to test new theories based on the findings of initial data. As such it is a theory-generating methodology and does not seek to test existing theories (Lingard et al., 2008). An important element of grounded theory is that the researcher approaches the data from a place of ignorance. There should be no predetermined hypothesis, no expectation of the results and no understanding of other work that might influence the research. In reality this can be difficult to achieve, and some would argue that it is counter-productive (Pope and Mays, 2006). For example, the

practicalities of truly approaching a research study with no understanding or knowledge of the literature surrounding it is almost impossible in academia given the need for literature reviews as part of funding applications.

In practice, most qualitative research is a kind of modified grounded theory, or 'grounded theory-lite', where researchers move between data collection and data analysis using a mixture of induction and deduction. The process of ascribing codes to all of the initial data is known as open coding and this develops the coding framework for subsequent data analysis. Axial coding (relating codes to each other) and selective coding (choosing a concept and relating codes to this concept) are then used in order to move towards the development of analytical categories through a process of constant comparison (Pope and Mays, 2006).

3.4.2 Thematic Analysis

In 2006 Braun and Clarke refined and defined a framework for analysis of qualitative data known as thematic analysis which is based upon grounded theory's inductive approach to identifying themes which emerge from the dataset (Braun and Clarke, 2006). It has been described as arguably the simplest form of analysis of qualitative data, and as such is the most commonly used in healthcare research (Braun and Clarke, 2014). In its most basic form it is "a method of identifying, analysing and reporting patterns (themes) within data" (Braun and Clarke, 2006). However, simply defining the themes that emerge from the data does not provide rich and useful data. A robust thematic analysis is then required to explore the inter-relation between the themes and to explain how these themes may or may not fit into different theoretical frameworks or models.

3.4.3 Computer-Assisted Qualitative Data Analysis Software

The process of ascribing codes to the qualitative data that has been gathered (in the form of transcripts or ethnographic fieldnotes) was historically a manual process involving index cards, Post-it® notes and a large space for mapping out codes and themes (Basić, 2010). The advent of computerised software designed to facilitate coding of qualitative data has improved efficiency (Bryman, 2008) and these software packages are collectively known as computer-assisted qualitative data analysis software (CAQDAS).

Text from interview transcripts, documents or fieldnotes can be highlighted and tagged with a code, and once coding is complete it is possible to view all text to which that code has been attached collectively, thus aiding the identification of emergent themes. While CAQDAS is useful in helping to collate coded text, it does not replace the role of the researcher in creating the codes, identifying the themes and analysing the data. While some have welcomed the advent of CAQDAS in qualitative data analysis for its potential to improve the rigour of the methods, others have criticised its potential to quantify qualitative research (Hesse-Biber and Leavy, 2010) and are concerned that it may lead to the researcher losing touch with the context in which the data were generated (Buston, 1997). It has, however, become the accepted method for coding qualitative data and is a mainstay of Campbell's paper (2013) presenting a standardised procedure for improving inter-coder reliability and agreement.

3.5 *Methods*

3.5.1 Ethical approval

The studies outlined in this thesis gained ethical approval from the University of Bristol Faculty of Health Sciences Research Ethics Committee, reference number 33021. The participant information sheets and consent forms can be viewed in Appendices 1 - 3.

Additionally, a veterinary UIN (ethical approval for an investigation involving animals) was issued for the study by Bristol University's Animal Welfare Ethical Review Body (Reference UB/16/051 Expiry 20/09/2019).

3.5.2 Selection and recruitment

For the measures of agreement between veterinary sales data, medicine book records and medicine bins, a sample size calculation was carried out *a priori* as described in Chapter 5. This suggested that a minimum of 23 farms were required, assuming a drop-out rate of 20%, therefore a target of 25-30 farms was agreed. Given the mixed methods nature of the project and the fact that there was a lone researcher collecting data across a large geographical area, a balance needed to be struck between a large enough sample to show significance for the quantitative work and a small enough sample size to realistically be able to complete the data collection within the timeframe and budget. Additionally, it was agreed that >25 farms were likely to provide a large enough pool of farmers for semi-structured in-depth interviews to achieve data saturation. However, if more interviews were required, additional recruitment of eligible farmers would be possible.

For the intensive participant observation work, a discussion was had between the lead researcher (GR), a human geographer (HB) and medical anthropologist (HL) about the number of farms required. Again, a balance was needed between having a large enough number of farms to be able to reflect the very different farm sizes and types in the UK while a small enough number was necessary in order to gather the rich data required of this type of research. While participant observations are usually focussed on one culture and context for their entirety (Emerson et al., 2011), it was decided that by including three

Methodology and methods

farms within the same broader context of geographical area, veterinary practice and social network but with different herd sizes, management types and production goals, a rich dataset which could better translate to the industry could be obtained.

Twenty-seven dairy farms from South West England and South Wales were recruited to the study. Farms were purposively recruited using maximum-variation sampling through a combination of direct approach, approach of a farm animal veterinary practice within the study area or by self-nomination following advertising on social media and at local agricultural shows. Where deemed appropriate, an approach to the veterinary practices was made by a Professor of Bovine Medicine (DB) in the first instance in order to improve the chances of a positive response and help with recruitment.

Nine veterinary practices within an approximately one-hour radius of Bristol Veterinary School at Langford, North Somerset and four veterinary practices within a one-hour radius of Carmarthen, Carmarthenshire were approached by email or telephone to request their assistance in recruiting farms to the project. A recruitment poster and flyers were provided which the practices could distribute to clients (APPENDIX 4). All veterinary practices agreed to advertise the project to their clients and/or nominate specific farms for enrolment. They were requested to nominate dairy farms of varying size, management type, production goals and medicine use.

The recruitment poster was made available online at the University's farm animal research group pages and was shared on social media sites, where any farmers within the study area who were interested were encouraged to get in touch.

Twenty-six farms were identified through their veterinary practices, with a further four farms making contact and expressing interest in enrolling in the study having seen or heard it advertised. All farmers identified were contacted by telephone in order to explain the scope and objectives of the research. Two farms decided not to enrol in the project after the initial contact, stating a lack of time. For farms that were interested during the telephone conversation, a time was arranged for a visit to the farm in order to discuss the details of the project further. All farmers were then sent a copy of the participant information sheet (APPENDIX 1 & 2) and consent form (APPENDIX 3) a minimum of 48 hours before being visited in person during June, July and August 2016. During this visit, the participant information sheet was explained, and farmers were encouraged to raise any questions or concerns they had about involvement in the project. One farm decided at this stage that they could not commit the time necessary to be involved in the wider project and declined involvement. The remaining 27 farms confirmed willingness to enrol in the project and consent forms were signed.

During the initial visit it was stressed that in order to ensure the success of the project it was important to maintain medicine purchase, storage and records in a normal, day-to-day way and not to deliberately change, improve or “tidy-up” the medicine cupboards or record books. The purpose of the study to observe and measure normal medicine use behaviours was emphasised, and participating farmers were reminded that the research was purely academic and in no way associated with farm assurance certification schemes or the usual medicine auditing to which farmers would be accustomed.

Farmers were also told that they would be asked to participate in a semi-structured in-depth interview about their use of veterinary medicine records at some point during the

next year which would last around an hour. Two farmers stated at this point that they would not be willing to participate in these interviews.

During these initial visits, three farms were identified as suitable for more in-depth participant observation. As described above, these farms were purposively sampled from the recruited pool of farmers to match the inclusion criteria: being located within the same geographical area (North Somerset), using the same veterinary practice and having the same wider social context (North Somerset dairy farmers) while also having different herd sizes, management types and production goals. These farmers were provided with a second participant information sheet tailored specifically for those farms involved in participant observation. The nature of their involvement in the participant observation was discussed and it was explained that the researcher would attend the farm on a semi-regular basis in order to participate in day-to-day activities and observe medicine use. This would involve visits approximately monthly over a 12-month period which would last a varying amount of time but usually around 4-6 hours at a time. It was explained that it was envisaged these visits would take place at different times, but the timings, lengths and nature of the visits would be inductive and iterative and later visits would therefore be targeted at time periods of high medicines use as determined during earlier visits. One farm was lost to the study after the initial inventory visit because they went out of business, so 27 farms took part in the cross-sectional study and 26 farms took part in the year-long medicine audit.

3.5.3 Farm medicine audits

In order to conduct the 12-month farm medicine audits, an initial medicine inventory was undertaken on each participating farm. This inventory is explained in greater detail in

Chapter 4 but briefly consisted of visiting each farm on the first day of the study and searching for, measuring and recording all PVM found. Record was made of medicine name, quantity, number of individual items, storage location and expiry date. Pictures were taken of the medicine storage areas and a structured questionnaire was completed gathering information on farm demographics, herd health and management protocols (Appendix 5). This initial visit followed a pre-prepared visit checklist (Appendix 6).

Farmers were then offered a choice of medicine waste bin size and number, with the option of either 60-litre or 120-litre bins depending on their estimate of the volume of waste medicines they would produce quarterly and depending on location convenience. Once selected, these bins were placed in areas identified by the farmer as being most convenient for use. Laminated signs were placed around the farm, especially near the medicine waste bins and any other disposal areas, reminding staff to use the medicine waste bins and providing a reminder of what to place in the bins (Appendix 7). Farmers were then asked to place all empty medicine packs (bottles, tubes, packaging, etc.), as well as any waste medicines being discarded into these bins from that point onwards. Bins were then emptied from each farm approximately every quarter (90 days +/- 20) at the farm and researcher's convenience. Bin audit farm visits followed a pre-prepared checklist (Appendix 8). The final visit was conducted at day 365 (+/- 3 days to accommodate for farmer and researcher convenience). This final visit involved removing all medicine waste bins and contents and conducting an exit inventory identical to the initial day one inventory.

Participating farmers were asked not to change anything about the way they recorded medicine purchase and use for the duration of the study unless this was intended for

reasons external to the project. On the final visit, participating farms were asked to provide the medicine records in whichever form they took. After the final visit, all nine veterinary practices were contacted, provided with a copy of the appropriate completed consent forms, and asked to provide the veterinary sales records for the duration of the study for each farm.

3.5.4 Semi-structured in-depth interviews

All recruited farmers who identified themselves as the primary treatment decision-maker were asked to participate in a semi-structured in-depth interview exploring their thoughts on medicine use, with the exception of the three farms involved in the participant observation study who provided numerous unstructured interviews throughout the course of the project. Interviews were conducted iteratively, with two initial pilot interviews followed by a further 18 interviews over the following 18 months. All interviews were conducted on the respective farm, face-to-face, by the author. The interviews were recorded using an encrypted dictaphone (Olympus DS-3500 Audio Voice Recorder), with additional notes taken as required. An interview topic guide was developed by the author in consultation with supervisors who could provide extensive experience either in dairy medicine (KR & DB) or semi-structured interview methodology (HB). This topic guide was piloted and adjusted as described in the subsequent section and can be found in Appendix 9.

Interviews were conducted in a semi-formal manner, usually in the farm office or farmhouse kitchen over a cup of tea. Participating farmers were all given the same introduction to the process, emphasising that there were no right or wrong answers, it was not a test and the focus of the interview was on their thoughts and opinions about

the way veterinary medicines were bought, stored, used and recorded on their farms. At the end of the interview, each participant was asked whether they had anything else to add or could think of any area that the interview had not covered which they thought was important.

3.5.5 Participant observation

The three participating farms which were recruited for the participant observation in addition to the medicine audit underwent the same Day One visit with inventory and placement of medicine waste bins. At this visit a subsequent participant observation visit was arranged, and the primary contact was asked what the most appropriate method of contact would be to arrange visits. Visits were initially scheduled to be monthly; however, the exact frequency was allowed to be flexible in order to accommodate for the focus on medicine use to represent the varying schedule and seasonal nature of dairy farming and therefore medicine use.

It was decided that the initial participant observation visit should involve attending a morning milking session at each of the three farms. The reasoning for this decision was multifactorial. Morning milking is a routine activity carried out across all three farms and was expected to provide insight into the management practices on each of the farms. Morning milking is the first time the farmer will see their cows each day and potentially identify animals requiring treatment; the task at hand also provides some opportunity for participation alongside observation. It was also postulated that attending morning milking (which began at 4 am, 5 am and 6.30 am on the three farms) would increase trust and help to build a relationship between the farmer and the observer.

Methodology and methods

After this first participant observation visit, subsequent visits were arranged by text message with the primary contact. Visits occurred as often as every three weeks and as infrequently as every eight weeks depending on the season and the specific context throughout the 12-month study period. Visits were arranged to encompass morning milking, afternoon milking, calf management, youngstock management, drying off and one veterinary fertility visit for each of the farms. During the initial visits, morning milking was confirmed as being the most useful source of data on medicine use practices and decisions, therefore the majority of the subsequent visits focussed on attending and participating in morning milking routines.

During the visits, it was decided that ethnographic field notes would be taken contemporaneously in order to maintain as accurately as possible a record of the observed events. Where possible, the author participated in routine activities, for example by wiping or pre-dipping teats in the milking parlour or by helping to carry buckets and make up feeds for the calves.

3.5.6 Piloting the research methods

Prior to commencement of the study, the research methods were piloted at the University of Bristol's dairy farm. This farm had 220 cows in milk, was run by a herd manager who made the overarching decisions about medicine and treatment protocols with the aid of one herdsman who was in charge of the milking and the majority of treatment administration, and one other staff member who was in charge of calf management.

An initial inventory of all the medicines present on each farm was conducted, followed by placement of one 120-litre medicine waste bin and two 60-litre bins. The large bin was placed in the dairy with one smaller bin in the milking parlour and the other in the calf

shed. Staff were asked to place all used medicines in these bins for a 30-day period during July 2016. Signs were placed near other waste bins on farm reminding staff to use the research bins for medicine waste, and signs were placed near the medicine bins explaining which medicines the bins should be used for.

After 30 days the bins were emptied, and the contents were counted. Expiry dates were checked and medicines which had expired prior to the start of the pilot study were noted. Any wasted medicines still within the packs was quantified and recorded. Medicine records for the 30-day period were obtained from the pilot farm's on-farm computerised records, and the veterinary sales data for the study period was downloaded from the University Farm Animal Practice's computerised clinical records. These data were collected with the aim of piloting the research design and therefore this data was not analysed further to assess agreement between methods.

Semi-structured in-depth interviews were conducted with the farm manager and the herdsman. A topic guide for these pilot interviews was prepared in consultation with the supervisors and sought to investigate the beliefs and values relating to the topics of veterinary medicine purchase, storage, recording and use. The interviews were conducted face-to-face in the farm office and recorded using an encrypted dictaphone (Olympus DS-3500 Audio Voice Recorder). The first interview lasted 69 minutes and the second lasted 61 minutes. Both interview recordings were sent to an external professional transcription service (Bristol Transcription Services Ltd.) to be transcribed. The transcripts were discussed with the supervisors and it was agreed that the topic guide had successfully elucidated interesting and pertinent information. Hence, it was agreed that the topic guide would remain unchanged for the subsequent interviews, albeit with scope to adjust

iteratively as the interviewing and analysis progressed. HB, a supervisor with extensive experience in the use of semi-structured in-depth interviews, provided positive feedback on interview technique and some guidance on improving technique such as using non-verbal encouragement rather than saying “OK” as it is less intrusive.

Participant observation was also piloted on this farm, with two morning milking sessions attended for a total duration of eight hours. This was in order to provide experience and practice in the techniques and to identify any major concerns with the practicalities of note-taking and observing on a working dairy farm. The only practical detail of note was the tendency for any notes taken to become contaminated with faecal material due to the sunken pit where the researcher and farmer stood in the milking parlour. Also, the noise of the milking machines was occasionally loud enough to obscure some of the conversation, but this was not considered a major issue.

Resource availability: Investigating the contents of medicine cupboards

Chapter 4 Resource availability: Investigating the contents of medicine cupboards

Published: Rees, G.M, Barrett, D.C., Buller, H., Mills, H.I. & Reyher, K.K. (2018) Storage of prescription veterinary medicines on UK dairy farms: a cross-sectional study. *Veterinary Record*
Published Online First: 09 November 2018. doi: 10.1136/vr.105041

Resource availability: Investigating the contents of medicine cupboards

4.1 *Abstract*

Prescription veterinary medicine (PVM) use in the United Kingdom is an area of increasing focus for the veterinary profession. While many studies measure antimicrobial use on dairy farms, none report the quantity of antimicrobials stored on farms, nor the ways in which they are stored. The majority of PVM treatments occur in the absence of the prescribing veterinarian surgeon, yet there is an identifiable knowledge gap surrounding PVM use and farmer decision making. To provide an evidence base for future work on PVM use, data were collected from 27 dairy farms in England and Wales in Autumn 2016. The number of different PVM stored on farms ranged from 9-35, with antimicrobials being the most common therapeutic group stored. Injectable antimicrobials comprised the greatest weight of active ingredient found while intramammary antimicrobials were the most frequent unit of medicine stored. Antimicrobials classed by the European Medicines Agency as critically-important to human health were present on most farms, and the presence of expired medicines and medicines not licensed for use in dairy cattle was also common. The medicine resources available to farmers are likely to influence their treatment decisions, therefore evidence of the PVM stored on farms can help inform understanding of medicine use.

4.2 *Introduction*

Farmers in the UK are in the relatively privileged position of being able to purchase and store prescription veterinary medicines on farm for use at a later date. While these medicines must have been specifically prescribed for an animal or group of animals in order to treat diagnosed disease, there is little knowledge about the way these medicines are being used once they leave the veterinary practice. This knowledge gap extends to the storage practices on farm, and there is very little evidence available describing the quantity, composition or locations of medicines stored on farms.

In order to understand the way in which dairy farmers in the UK are using PVM, it seems logical to begin by measuring what PVM resources farmers have available when making treatment decisions on farm. A number of sociologists and cultural anthropologists have recently begun to point out that material objects – their presence, availability and accessibility – are increasingly recognised as playing an important role in the organisation, performance and normalisation of daily practices and labour (Riggins, 1994, Shove and Southerton, 2000). In this chapter, medicines, medicine bottles and medicine cupboards – their materiality and their accessibility – contribute directly, it is argued, to the treatment decisions and practices undertaken on the farm. A farmer is unable to treat an animal with a medicine he or she does not have. Equally, the availability of particular product will influence the subsequent treatment practice.

These resources provide some of the context within which treatment decisions are made and necessarily influence such decisions since a farmer is unable to treat an animal with a medicine he or she does not have. Of course, farmers are able to drive to their veterinary practice during opening hours to collect medicines as long as they are prescribed to the farm, or they are able to call a veterinary surgeon to the farm and obtain medicines in this way. However, on a routine, day-to-day basis the treatment decisions on the farm are limited to the medicines that farm has readily available.

In addition to understanding the resources available to farmers when making treatment decisions, examination of the current literature addressing medicine storage and use has identified various other knowledge gaps. Medicine storage on farms is an important part of compliance with Health and Safety Executive and farm assurance guidelines (Health and Safety Executive, 2012, Red Tractor Assurance, 2017), which require PVM to be placed in a secure, lockable location away from children, animals and thieves (Carr and Smith, 2013). In addition, medicines should be stored at the temperature requirements stated on the packaging. Despite this, a recent study found that vaccines were routinely being stored at inappropriate temperatures on UK farms (Williams and Paixao, 2018). There is currently little evidence available to determine whether PVM are used in the way the prescribing veterinary surgeon intended, or whether farmers are making decisions based on other factors while using stored PVM which may be expired or not licensed for use in dairy cattle.

That prescription medicines are often stored in the home for use at a later date has been documented in human medicine, despite the prescription intending immediate use (Tsiligianni et al., 2012, Abou-Auda, 2002). In fact, it has been shown that a proportion of patients deliberately plan to stop taking a course of prescribed antibiotics early in order to have a supply for self-use in the future (Hawkings et al., 2008, Shehadeh et al., 2012). Non-compliant use of medicines is commonly seen and there is a broad evidence base demonstrating that medicines are taken in ways other than that indicated by the prescriber (van der Geest et al., 1996). Patient nonadherence to prescribed treatment regimens has been framed as a complex and pervasive challenge. Either through misunderstanding, forgetting or ignoring healthcare advice, patients are commonly non-adherent, and this behaviour is influenced by subjective norms, beliefs, attitudes and the cultural context (Martin, 2005).

Household medicine storage is an area which has attracted some research in the human medical field, although often in countries with less rigorous prescription legislation and easier access to over-the-

Resource availability: Investigating the contents of medicine cupboards

counter or illicit medicines. A study of medicine storage in rural Cretian households showed that people stored a large amount of medicines under inappropriate conditions and regularly shared medicines between family and friends (Tsiligianni et al., 2012).

There are many studies measuring antimicrobial use on dairy farms, however none report the quantity of antimicrobials stored on farms directly, nor the way in which they were stored. Equally there is a dearth of information about the storage of other PVMs, vaccines and endectocides.

As described in Chapter 2, 98% of dairy farms are members of the Red Tractor Farm Assurance Scheme (Responsible Use of Medicines in Agriculture Alliance, 2017) and, as such, are required to undergo annual farm assurance audits, as set out in the Red Tractor Dairy Standards (Red Tractor Assurance, 2017). The ultimate aim of farm assurance is to provide the consumer with a guarantee that producers of food meet minimum standards of food safety, animal welfare and myriad other attributes (Bailey and Garforth, 2014). However, there is evidence to show that these farm assurance visits and the associated health plans are seen as a “waste of time” and “tick box exercise” by some producers (Escobar, 2015) while others find some inherent value (Bailey and Garforth, 2014). Either way, the occurrence of these visits has led to an expectation that medicine storage will be scrutinised on a semi-regular basis.

In order to provide data on the storage practices of PVM on UK dairy farms and to investigate the quantity and composition of PVM being stored a cross-sectional study of medicine cupboards on 27 dairy farms was conducted in September and October 2016. Farm demographic and management data were collected alongside a full audit of the PVM present on the farm on the study day.

4.3 Methods

This chapter was written according to the Strengthening the Reporting of Observational Studies in Epidemiology statement for scientific reporting of cross-sectional studies (Elm et al., 2008). Participant recruitment, ethical approval and consent are as previously described in Chapter 3, subsections 3.5.1 and 3.5.2.

4.3.1 Data collection

All 27 participating farms were visited once between 13th September and 18th October 2016. This visit occurred at a date and time convenient for the farmer and was arranged in the preceding week by telephone. On the day of the visit, the author (GR) explained the purposes of the study once more to the participant, along with the initial visit objectives as described in Chapter 3. A structured interview was conducted, and the designated medicine cupboard was examined first along with certain high-probability storage areas that were directly enquired about (e.g. household refrigerator, calf shed, milking parlour). Permission was also requested to search for PVM anywhere on the farm. A photograph of the medicine cupboard was taken and fieldnotes written as an *aide memoire* about the storage systems.

4.3.1.1 Medicine database

A database of all POM-V medicines licensed for use in cattle in the UK was created by the researcher (GR) before commencement of the study (Appendix 10). The Veterinary Medicines Directorate (VMD) publish a list of UK-licensed veterinary medicines (Veterinary Medicines Directorate, 2018b) in Excel (Microsoft Office 365) which was downloaded and modified to contain only those medicines used in cattle. Additional data were added to this database, including the concentration of the active ingredient present, the minimum, maximum and median dose rate and course length, the dose unit (mg/kg, tube/cow etc) and the pack unit (ml, g, dose). These additional columns in the spreadsheet were added manually and populated with data sourced from either the Specified Product

Resource availability: Investigating the contents of medicine cupboards

Characteristics (SPC) which are published for every licensed veterinary medicine in the UK, or from the NOAH Compendium of Datasheets 2017. These data entries were checked by the author by selecting the last two medicines beginning with each letter of the alphabet and double checking that there were no data entry errors. This database was then further validated by a research associate (HS) from the University of Bristol who selected a random sample of 10% of the data and ensured the inputted values were correct.

Once complete, the database was sent back to the VMD who further checked and validated the data and entered further data points such as duration factors and antimicrobial use metrics. Following discussion with various stakeholders after creation of this database, it was decided that there was a need for this database to be published online under a Creative Commons Licence in order to aid other researchers and veterinary surgeons and to try and prevent a duplication of efforts. This process is currently ongoing.

In addition to this main medicine information reference database, further databases were created for each participating farm, which contained the VMD's list of licensed veterinary medicines alongside specific columns for inputting data collected on farm during the initial inventory (Appendix 11). A separate sheet in each farm's individual database contained the structured questionnaire, with limited response options where appropriate.

4.3.1.2 Structured survey

On the day of the medicine cupboard audit, a structured interview was conducted with the self-identified "main treatment decision-maker" (hereafter called the farmer) in order to gather information on farm demographics, management principles, health and productivity data (Appendix 5). This questionnaire had been designed, piloted and refined as described in Chapter 3. Stock numbers, production values, health and fertility data were ascertained to the best of the farmer's

Resource availability: Investigating the contents of medicine cupboards

knowledge at the time of the visit, aided by consultation with on-farm records. This questionnaire took approximately 20-30 minutes to complete, with the researcher asking a series of questions and inputting the data directly into the pre-prepared spreadsheet.

4.3.1.3 *Medicine Inventory*

Once the structured survey had been completed, the farmer was asked to indicate all areas on the farm where PVM were found. The designated medicine cupboard was examined first, and certain high-probability areas were enquired about (e.g. did the farmer store any medicines in the house or in the home refrigerator? Were there any medicines in any of the farm vehicles?). Farmers were also asked for permission to search for veterinary medicines anywhere on the farm and were then informed that they could continue with their work and leave the researcher to the search. The length of time taken to inventory PVM ranged from 45 minutes to 90 minutes and was largely dependent on the number of locations where medicines were present, the amount of PVM stored and the general orderliness of storage, which varied greatly between farms. For the purposes of this study, medicine storage was described as being suitable if it fit the definition given by the VMD in the Code of Practice for the Responsible use of animal medicines on the farms (Veterinary Medicines Directorate, 2014a). This states that medicines should be kept at the appropriate temperature and under the conditions stated by the packaging. The Code suggests that medicines should also be kept in their original packaging, be clean and stored where possible in a locked and secure place.

All PVM found were entered on-location into a pre-prepared spreadsheet (Appendix 11). Location, drug name, pack size, number of packs, quantity remaining in each pack and expiry dates were noted. Where the product label was illegible it was disregarded. Where the expiry date was illegible it was assumed to be within date. Volume remaining was estimated by eye to the nearest 10% of pack size (i.e. for a 100 ml pack of liquid, volume was estimated to the nearest 10 ml and for a 50 g pack of

powder, quantity was estimated to the nearest 5 g). All POM-V medicines were recorded along with any vaccines licensed for use in cattle and all pour-on, oral and injectable endectocides (anthelmintics). Vaccines were recorded in number of doses rather than volume. All intramammary and ocular medicines were recorded as single units per tube because one tube is equivalent to one dose.

4.3.2 Data analysis

Data from each farm's individual inventory spreadsheet were then collated and analysed by retrieving specific datasets through R software (R Core Team 2012) and producing a database for all 27 farms to be compared and analysed together. The structured survey data were analysed descriptively.

Medicine quantities were measured in total mg of active ingredient present, in mg per population corrected unit (PCU) in-line with nationally reported use data (Veterinary Medicines Directorate, 2016) and in total number of "medicine units" present. Medicine units were defined as: one bottle of liquid, one tube of intramammary or ocular suspension, one pack of boluses or tablets, one container of powder or one tube of ointment. Prescription veterinary medicines were grouped according to therapeutic group (e.g. antimicrobial, vaccine). Antimicrobials were grouped by antimicrobial class (e.g. penicillin, fluoroquinolone) and according to route of administration (e.g. injectable, intramammary). Expired medicines were defined as those medicines with an expiry date prior to the day of the inventory. Milligrams of active ingredient were presented to the nearest 100 mg for the total weight of active ingredient, to the nearest 10 mg for mg per cow in milk and mg per 1000 litres of milk produced annually and to the nearest 0.01 mg for mg/PCU.

Data was visually checked for normality. Normally distributed data were reported as a mean with standard deviation in brackets. Non-normally distributed data were reported as a median with range in brackets. Calculations were performed using a combination of Microsoft Excel (2016) and R (R Core

Resource availability: Investigating the contents of medicine cupboards

Team, 2012). Given the cross-sectional, point-prevalence nature of the dataset and the fact that the study farms are not intended to be a representative sample of the population, presented calculations were descriptive and no inferences on causality can be made.

4.4 *Results*

4.4.1 Farm Demographics

Thirty-four dairy farms were identified as eligible for the study through self-nomination or nomination by veterinary practices. All were invited to enrol in the study, and 29 agreed to take part. Two farms dropped out of the study before the medicine inventory visit. Data for the remaining 27 farms was complete. These farms were located across seven counties and were under the care of nine different veterinary practices.

Table 4:1: Demographic and management characteristics of the 27 participating farms

Characteristic	Response	Number of farms (n)
Age of farmer (years)	18-30	5
	31-40	5
	41-50	5
	>50	12
Education level of farmer	Basic schooling	3
	O Level/GCSE/A Level	4
	HNC/HND/NVQ	16
	University bachelor's degree	4
Total herd size	100-199	6
	200-299	12
	300-699	10
	>700	5
Total number of cows in milk	1-99	5
	100-199	11
	200-299	4
	>300	7
Calving pattern	Year-round	22
	Seasonal – Spring	4
	Seasonal – Autumn	1
Primary cow type	Holstein	16
	British Friesian	4
	Channel Island	3
	Crossbreed	2
	Other	2
Waste-milk feeding	Yes – all calves	13
	Yes – beef calves only	7
	No	7
Dry cow antimicrobial therapy	Blanket therapy	18
	Selective therapy	9

Definitions: Farmer = self-described main treatment decision-maker; Basic schooling = no qualifications gained; GCSE = General Certificate of Secondary Education; HNC = Higher National Certificate; HND = Higher National Diploma; NVQ = National Vocational Certificate; Blanket therapy = all dry cows treated with intramammary antimicrobial; Selective therapy = certain dry cows not treated with intramammary antimicrobial based on somatic cell count and mastitis risk assessment

Farm demographic and management characteristics are described in Table 4:1. In summary, the median total herd size was 320 with 175 cows in milk. Most farms (59%) described the main cattle breed as Holstein and the majority calved year-round (81%). The median total annual milk volume per herd produced was 1.1 million L with annual milk sales per cow of 7500 L. Seventy-four percent of farmers had some formal specialised education and training in agriculture.

Resource availability: Investigating the contents of medicine cupboards

Table 4:2: Production, health and medicine storage characteristics of the 27 participating farms

Property / characteristic	Median or Mean*	Range (Median) or SD (Mean)*
Total herd size	320	119 – 1,271
Number cows in milk	175	65 – 600
Total annual milk volume (million L)	1.1	0.5 – 4
Total annual milk sales per cow (L)	7500	3,600 – 11,300
Milk price (pence per L)	22.5*	15.3*
Somatic cell count (cells per ml)	176,407*	50,466*
Bactoscan (1,000 bacteria per ml)	20.9*	7.5*
Mastitis (cases per 100 cows per year)	36.7*	15.9*
Lameness (cases per 100 cows per year)	22.2*	15.3*
Respiratory disease (cases per 100 calves per year)	10	0 – 47
GI disease (cases per 100 calves per year)	10	3 – 59
Number PVM present on farm (by active ingredient)	19	9 – 35
Number PVM present on farm (by medicine unit)	101	28 – 339

Median = non-normally distributed data Mean = normally distributed data

Definitions: PVM = Prescription veterinary medicines. L = Litre. SD = Standard deviation. GI = Gastrointestinal

Formatted: French (France)

Farm production and health characteristics are presented in Table 4:2. Two-thirds of farms used blanket dry cow therapy (where all cows were dried off with intramammary antimicrobial treatment). Twenty farms routinely fed waste milk containing antimicrobial residues to beef calves, 13 of which also fed waste milk to dairy replacement calves. The mean number of clinical cases of mastitis and lameness per 100 cows per year was 36.7 and 22.2 respectively. There were a median of 10 cases of respiratory disease and 10 cases of gastrointestinal disease per 100 calves per year.

4.4.2 Storage methods & labelling

Medicines were stored in six different location types across the study farms as seen in Figure 4-1. Most were stored in a lockable medicine cupboard or refrigerator although 29% were stored in a non-compliant area such as the milking parlour, the calf shed or the office. Ten farms stored 100% of their medicines in lockable medicine cupboards or lockable refrigerators, and two farms did not store any medicines in a lockable medicine cupboard or lockable refrigerator. No participating farm monitored the temperature of their refrigerator or medicine storage area.

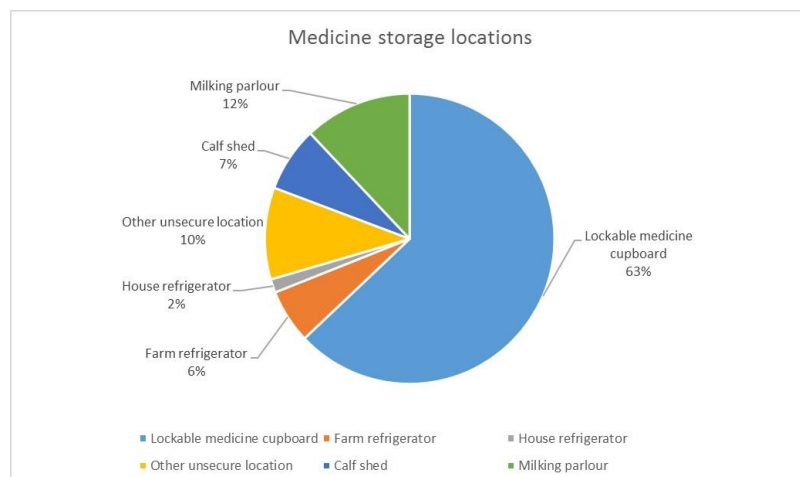


Figure 4-1: Medicine storage locations on the 27 participating farms

Subjectively, medicines were stored in a variety of different ways, with some farms having a systematic and ordered storage system and others having seemingly random storage of old, new full and empty medicine units. Of the PVM stored, 53.6% carried the recommended prescription label from the prescribing veterinary practice. For antimicrobials, this figure rose to 65.1% for all antimicrobials and 74.1% for injectable antimicrobials. At the farm-level the prevalence of labels on antimicrobials ranged from 6.25 - 100%.

4.4.3 Prescription Veterinary Medicines

There were a median of 19 (9-35) different types (by active ingredient) of PVM and 101 (28-339) individual medicine units of PVM present on participating farms. Antimicrobials were the therapeutic group most commonly stored both by frequency of occurrence (median 69 (22-296) medicine units) and by total weight (median 182,300 (45,500 – 442,500) mg) equivalent to 1.54 mg/PCU.

Resource availability: Investigating the contents of medicine cupboards

4.4.3.1 Antimicrobials

The route of administration for antimicrobials stored are presented in Table 4:3. Of the total antimicrobials stored across all farms 76.4% were injectable and 14.7% were intramammary. When units were measured, 10% were injectable (bottles) and 84.8% were intramammary tubes.

Table 4:3: Total quantities of antimicrobial stored across all 27 participating farms, by route of administration

Route of administration	Total (mg)	Total (medicine units)
All	5,127,176 (100%)	2,801 (100%)
Injectable	3,917,116 (76.4%)	280 (10%)
Intramammary	755,772 (14.7%)	2,374 (84.8%)
Topical	284,348 (5.5%)	51 (1.8%)
Oral	54,440 (1.1%)	31 (1.1%)
Intrauterine	115,500 (2.3%)	65 (2.3%)

Data on antimicrobial storage is presented in Table 4:4. Total HP-CIA storage per farm was a median of 10,000mg, or 0.12 mg/PCU with the majority (5000mg) being 3rd generation cephalosporin. Injectable antimicrobials comprised the greatest total weight with a median of 143,600mg or 1.19 mg/PCU, compared with intramammary antimicrobials which were a median of 21,200mg or 0.21 mg/PCU. Conversely, intramammary antimicrobials had the greatest total number of medicine units present, with a median of 66 units compared with 9 units of injectable antimicrobials.

Resource availability: Investigating the contents of medicine cupboards

Table 4:4 Total quantity of antimicrobial stored on all 27 participating farms

Antimicrobial type	Total (mg)		Total (mg/PCU)		Total (Medicine units)		Number of farms where present
	Median	Range	Median	Range	Median	Range	
Total antimicrobial	182,200	45,500 – 442,400	1.54	0.51 – 5.08	69	22 – 296	27
Total HP-CIA	10,000	0 – 68,000	0.12	0.00 – 0.34	5	0 – 95	24
Fluoroquinolone	0	0 – 32,000	0.00	0.00 – 0.19	0	0 – 4	11
3 rd gen. cephalosporin	5,000	0 – 36,000	0.06	0.00 – 0.30	1	0 – 5	19
4 th gen. cephalosporin	1,000	0 – 9,000	0.01	0.00 – 0.12	0	0 – 59	13
Injectable (all)	143,600	16,500 – 393,000	1.19	0.19 – 4.51	9	1 – 35	27
Intramammary (all)	21,200	1,000 – 111,400	0.21	0.01 – 0.49	66	5 – 248	27
Other (all)	13,200	0 – 61,800	0.11	0.00 – 0.63	5	0 – 24	21
Injectable (HP-CIA)	5,000	0 – 36,000	0.09	0.00 – 0.34	2	0 – 6	24
Intramammary (HP-CIA)	1,000	0 – 9,000	0.01	0.00 – 0.12	0	0 – 93	12
Other (HP-CIA)	0	0	0.00	0.00	0	0	0

Definitions: HP-CIA = Highest Priority Critically Important Antimicrobial; 3rd gen. cephalosporin = 3rd generation cephalosporin; 4th gen. cephalosporin = 4th generation cephalosporin

Eighty-nine percent of farms stored at least one HP-CIA. The most frequently occurring injectable antimicrobials were ceftiofur (a HP-CIA; n=24) and penicillin/streptomycin combination (n=24). Also commonly found were oxytetracycline (n=22), tylosin (n=19) and trimethoprim/sulfadiazine (n=16). The three lactating-cow intramammary antimicrobials most commonly identified were potentiated amoxycillin (n=11), the combination streptomycin/neomycin/novobiocin/penicillin (n=11) and cefalexin/kanamycin (n=10). The most frequently occurring dry cow intramammary antimicrobials were cephalonium (n=12), cefquinome (a HP-CIA; n=10) and cloxacillin (n=8).

The total mg/PCU on each farm ranged from 0.51 - 5.08 mg/PCU (Figure 4-2). Total mg per cow in milk ranged from 430 – 3,430 mg (Figure 4-3). Total mg per 1000 litres of milk produced annually ranged from 40 – 740 mg (Figure 4-4).

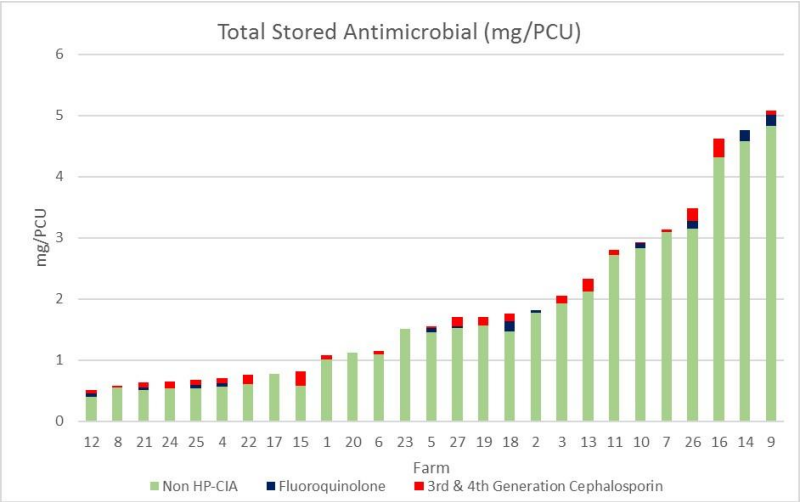


Figure 4-2: Total quantity of antimicrobial stored in mg per population corrected unit (PCU) for each of the 27 participating farms

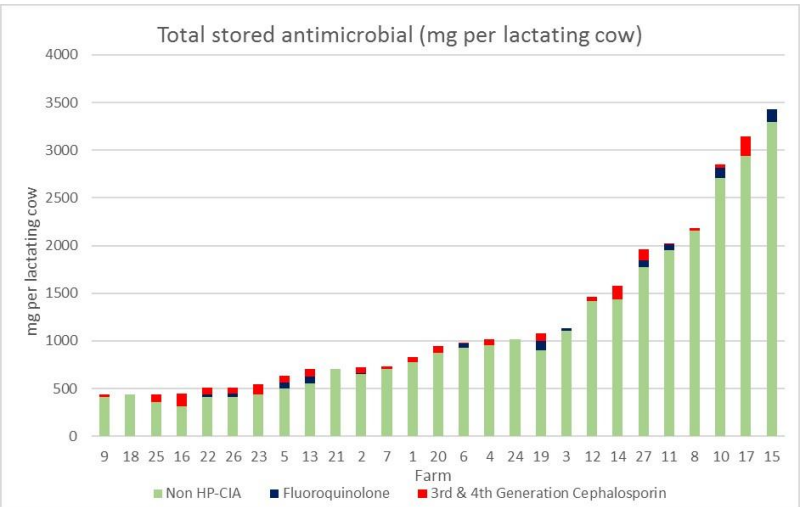


Figure 4-3: Total quantity of antimicrobial stored in mg per lactating cow on each of the 27 participating farms

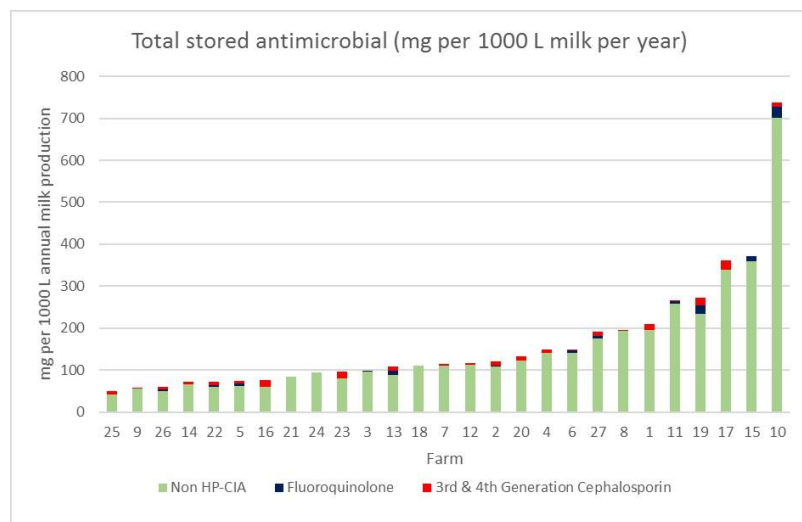


Figure 4-4: Total quantity of antimicrobial stored in mg per 1000 litres of milk produced annually on each of the 27 participating farms

4.4.3.2 Vaccines & Other PVM

The total number of vaccine doses stored across all farms was 3,541 with a median of 0 (0-1893) doses per farm. Eighteen farms (66.7%) stored no vaccines at the time of the study. The most common diseases for which vaccines were stored were Bovine Herpes Virus-1 (866 doses; 5 farms), leptospirosis (835 doses; 5 farms) and bovine viral diarrhoea (BVD) (683 doses; 5 farms). Other diseases for which vaccines were stored were calf diarrhoea, bluetongue, clostridial diseases, lungworm, mastitis and calf pneumonia.

The total number of units of NSAIDs across all farms was 75, with a median of two per farm (0-8). The total number of anthelmintics or anti-protozoals present across all farms was 87, also with a median of 2 per farm (0-14). The total number of units of hormone across all farms was 53, with a median of 1 (0-10) unit per farm. Five farms (19%) stored prostaglandins.

4.4.4 Expired medicines

At least one unit of expired PVM was stored on 25 farms (93%). Eighteen farms (67%) stored at least one expired antimicrobial and six (22%) stored at least one expired vaccine. The total number of expired antimicrobial units across all farms was 201, with each farm storing a median of 2 (0-58) expired antimicrobials. The total number of doses of expired vaccines stored across all farms was 827, with each farm storing a median of 0 (0-725) expired doses.

The median length of time since expiration was 12 (1-200) months. For antimicrobials, median length of time since expiration was 10 (1-96) months, for anti-inflammatories 6 (2-42) months, for vaccines 20 (2-200) and for other medicines 12 (2-120) months, with the majority of the “other” medicines endectocides.

4.4.5 Cascade medicines

Medicines not licensed for use in dairy cattle were found on 16 farms (59%). A total of 30 unlicensed units were stored comprising 14 different medicines. Seven different unlicensed antimicrobials were identified totalling 709,100 mg of active ingredient. Macrolides were most common with 138,600 mg of erythromycin (licensed for use in poultry and pigs) found across seven farms served by two different veterinary practices - 2,000 mg lincomycin on one farm (licensed for use in pigs) and 200 mg gentamycin (licensed for use in horses not producing milk or meat for human consumption) on one farm. Also found were 500,000 mg of tetracyclines (licensed for use in poultry and pigs) across three farms served by one veterinary practice, 5,000 mg metronidazole veterinary tablets (licensed for use in dogs and cats but banned from use in cattle) on one farm, 18,000 mg of 1st generation cephalosporin of Hungarian origin and not licensed for sale in the UK on one farm and 30,000 mg of florfenicol of Dutch origin not licensed for sale in the UK on a different farm. There was no clustering of unlicensed products by farm. Other unlicensed medicines identified were: 50 ml of mepivacaine (a local anaesthetic agent licensed for use in horses), 1 tube of acepromazine gel and 30 ml romifidine

Resource availability: Investigating the contents of medicine cupboards

(sedatives licensed for use in horses), 2 capsules of 2 mg loperamide (an antispasmodic licensed for human use), 200 ml sucralfate, 2 tubes of fusidic acid gel (an antibiotic topical gel licensed for use in cats and dogs) and one bottle of topical miconazole licensed for use in dogs. Where unlicensed medicines were found, farmers confirmed they were present for use in the dairy calves or adult cattle.

4.5 *Discussion and Conclusions*

Most farms in this study stored PVM in the recommended way. However, some PVM were being stored in inappropriate conditions e.g. in areas at risk from heat or cold damage and exposure to sunlight or gross contamination. Twenty-nine percent of PVM found were not stored in a lockable cupboard or room. This has direct health and safety implications due to access to potentially harmful medicines by animals or children in addition to risks of theft. Certain medicines should be stored with particular care due to their potential for harm from accidental exposure (Carr and Smith, 2013). Prostaglandins for example, which made up a proportion of the hormone POM-V reported in the results section, can be absorbed transcutaneously and lead to miscarriage or serious and even fatal respiratory compromise in susceptible people (NOAH, 2017).

While some farms stored a wide range of different types and quantities of PVM, others stored a limited number. The fact that the quantity of antimicrobials stored on farm does not appear to be linked with the number of animals at risk of treatment or the overall production values of the cows on the farm (Figures 4-2, 4-3 and 4-4) suggests that there are other reasons for the range of storage practices seen.

As previously noted, a farmer's treatment decisions are to some extent constrained by the PVM resources available to them. It follows therefore that when designing policy interventions aimed at reducing AMU, data on storage practices and farmers' use of stored medicines is extremely important.

4.5.1 Antimicrobial storage

Antimicrobials were the PVM stored in the greatest quantity when measured by total mg of active ingredient as well as by individual medicine units. Twenty-four farms stored HP-CIAs indicating that their use is still common in UK dairy farming, however recent increased efforts to reduce their use mean this is likely to be a rapidly evolving picture. For example, as of June 2018 Red Tractor Farm Assurance require HP-CIAs only be used as a last resort, with a veterinary report outlining diagnostic or sensitivity testing (Red Tractor Assurance, 2018). While storage does not equate to actual use, it is likely that these antimicrobials are stored with the intention of use and therefore it may be that the use of HP-CIAs was still common practice during the period of the study. Data from the wider longitudinal research study is in preparation for publication and will report on actual PVM use on these farms including HP-CIA use over a 12-month period.

The number of bottles of injectable antimicrobial present on farms was as high as 35 on one farm, with a median of 9. Keeping a store of antimicrobials like this provides a large resource for the farmer to use without a need to consult her/his veterinary surgeon. One of the most frequently kept injectable antimicrobials was ceftiofur, a HP-CIA. Given the focus on reducing the use of HP-CIAs in the years preceding the study, this may be indicative of a reluctance to move away from their use in the dairy sector. The 0-hour milk withhold carried by ceftiofur and its broad licensing for use in respiratory disease, metritis and interdigital necrobacillosis made it an attractive and cost-effective option for treating disease on farm, and it appears to have remained popular at least until the latter part of 2016. The antimicrobials most commonly used for treating mastitis in the lactation period were not on the current HP-CIA list although potentiated amoxycillin is not considered to be a first-line treatment (World Health Organisation, 2016). The most commonly stored antimicrobials for treating dry cows included cefquinome, a 4th generation cephalosporin and HP-CIA.

Many of the first-line, “responsible” antimicrobials have a relatively high total weight of active ingredient when compared with HP-CIAs, leading to calls for HP-CIAs to be measured and benchmarked separately from other antimicrobials (Mills et al., 2018, Hyde et al., 2017). This study provides evidence that there is an ongoing need to change behaviour and reduce the use of HP-CIAs on dairy farms.

Interestingly, when measured in mg/PCU or mg/1000L milk produced annually, the data show that while most farms stored similar quantities of antimicrobials, a handful of farms stored up to ten times as much as those farms which stored the smallest amounts. This suggests other factors affect the storage practices of dairy farmers.

Participating farms stored a broad range of different antimicrobials, thus increasing their options when making treatment decisions. This could lead to a dissonance between the intention of the prescribing veterinary surgeon and the actions of the farmer. Having such a large resource to draw upon could be seen to improve the agency and ownership of the farmer on those decisions, but conversely to decrease the agency and ownership of the veterinary surgeon legally responsible for their use. This serves to emphasise the importance of understanding the treatment decisions, given the relatively few resource constraints.

4.5.2 Labelling

While there is no legal requirement for labelling of PVM provided they are supplied in their original packaging, both the VMD and the RCVS consider it good practice for all PVM to carry a dispensing label (British Small Animal Veterinary Association, 2017). These labels must not obscure the batch number or expiry date. The RCVS Practice Standards Scheme requires labels to contain the following information: name and address of the animal owner/client, name and address of the veterinary practice supplying the medicine, date of supply, name, strength and quantity of product, dosage and

directions for use, the statement 'For animal treatment only' and for topical preparations 'For external use only' (Royal College of Veterinary Surgeons, 2018). The lack of appropriate labels found on the medicines stored across the participating farms may reflect the fact that many practices are still labelling the external cardboard packaging (which is often discarded upon purchase) as opposed to the actual medicine packaging. Additionally, some farms do not store prescription intramammary medicines in the original boxes, and individual intramammary tubes are rarely labelled. This lack of labelling often means there is no indication of the dose required for injectable PVM, as only some PVM contain this information on the manufacturer's label.

4.5.3 Expired medicines

While the presence of expired medicines does not equate to their use, the fact that expired PVM were identified on most participating farms indicates that their use is likely to be common. Expiry dates for drug products are set based on real-time stability testing at appropriate storage conditions to determine whether the drug substance meets its individually set specification (European Medicines Agency, 2003). A specification "establishes the set of criteria to which a drug product should conform to be acceptable for its intended use" (European Medicines Agency, 1999). All but two farms stored at least one expired PVM with two-thirds storing at least one expired antimicrobial. This is particularly striking when compared with studies of household medicine storage among human health, which have shown a range of 3-22% of stored medicines were expired (Zargarzadeh; et al., 2005, Teni et al., 2017). Given the average length of time passed since expiry was 12 months, with one farm storing medicine that was over 16 years out-of-date, their presence appears to be accepted by farmers on dairy farms.

The impact of using an expired antimicrobial is ill-defined. It is assumed that the efficacy of an antimicrobial, or indeed any medicine, reduces with time after expiration. However, the evidence base

for this is small and contradictory. In one study from human health, it was shown that there was a decreased rate of pathogen susceptibility to expired antimicrobials (Ogunshe and Adinmonyema, 2014). Other studies have shown that most medicines retain their efficacy for many years beyond their expiration date (Courtney; et al., 2009, Cantrall; et al., 2012). To the authors' knowledge there are no studies on the efficacy of expired antimicrobials in veterinary medicine.

Perhaps more important than the expiry date stated on PVM is the shelf life of the medicine once broached. In-use shelf life is determined for multi-use veterinary products by in-use stability testing of physical, chemical and microbial properties. Products approaching the end of their shelf life are tested, with testing designed to simulate as closely as possible real-life conditions based on likely usage patterns of the product under "normal environmental conditions" and stored according to the product literature. These drugs are measured against either their original specification or an "in-use shelf life" specification, as appropriate (European Medicines Agency, 2001). While this is often 28 days for injectable products and 24 hours for vaccines, in reality these shelf lives are rarely observed due to most injectable medicines being sold in multi-dose bottles and individual animals' treatment courses require varying volumes of medicine. Measuring the presence and use of PVM that had passed its broached shelf-life was beyond the scope of this study, however future research in this area would be valuable.

Expired or waste PVM should not be disposed of with normal household waste and most veterinary practices offer a disposal service to clients. Given the prevalence of expired PVM on the study farms, veterinary surgeons should determine whether the farms under their care are disposing of these medicines appropriately or whether they remain on farm with potential for use. Discussion of the use and disposal of expired PVM would make a valuable addition to herd health review meetings,

Resource availability: Investigating the contents of medicine cupboards

particularly given the veterinary surgeon's ultimate responsibility for the safety of medicines being used in these food-producing animals.

4.5.4 The Cascade

Using PVM which are not licensed for use in dairy cattle is not illegal if they are prescribed and used according to the Cascade and where there are established Maximum Residue Limits (Veterinary Medicines Directorate, 2015b). However, the use of unlicensed PVM is not currently monitored in the UK. Given the presence of medicines which have been prescribed via the Cascade further research is urgently needed in this area. In one instance, PVM were present which are explicitly banned from use in dairy cattle (metronidazole): administration would constitute a transgression of the law (European Union, 2009).

4.5.5 Study limitations

The use of purposive sampling through veterinary practice nomination inevitably leads to the possibility of selection bias. The study farms were demographically reflective of the wider UK dairy farm population. According to the AHDB the "average number of adult dairy cows" on UK dairy farms in 2016 was 143 (Agriculture and Horticulture Development Board, 2016), compared to the study farm median of 175. The larger herd size of the study farms may influence the way in which PVM are stored. Larger herds are more likely to have an increased frequency of veterinary visits which may mean they store fewer PVM on the farm as they have additional resources available to them through the veterinary surgeon on a regular basis.

Farmers were asked not to alter the medicines stored on their farms for the visit day. Given the prevalence of expired medicines and storage of medicines outside of designated cupboards it appears that farmers did not significantly improve their storage practices prior to the visit, and it is believed that the data described are representative of normal medicine storage on the study farms. The volume

of medicines in opened bottles was estimated by eye to the nearest 10 ml, which may have led to some over- or under-estimation of the total volume present on farm. Using reference weights for different medicines and a portable weighing scale to measure the weight of bottles may have improved the accuracy of these measurements.

This study was cross-sectional, and the seasonal nature of dairy farming and disease prevalence should be noted. This study took place in the Autumn, around the time of housing for many farms, and the data may be different if it was to be repeated in different seasons. For example, infectious disease prevalence can increase during the housed winter months for certain diseases, and farmers may be likely to store more antimicrobials or anti-inflammatories in anticipation of an increased need for use at this time. This could lead the study to overestimate typical storage levels on farms, where much less PVM might be found in the summer months. Where mixed-enterprise farms were included, these stored medicines intended for use in dairy cattle and calves separately from medicines intended for beef or sheep. This did not allow for any measurement of the possibility of medicines stored for use in beef and sheep being used in the dairy cattle. It is also important to note that this study reports storage practices on a small number of dairy farms in South West England and South Wales and as such may not reflect practices found on other farms or in other regions of the UK. Further research in this area is needed to provide a robust evidence base for future policy decisions aimed at improving responsible medicine use in dairy farming.

4.5.6 Implications for medicine use

While it has been highlighted before that veterinary surgeon must assume responsibility for providing advice on security, storage, hygiene, use and disposal of PVM (Carr and Smith, 2013), it would appear that, at least among study farms, more could be done to effect behaviour change and bring about responsible storage practices. As suggested, the inclusion of these important areas in the annual herd

Resource availability: Investigating the contents of medicine cupboards

health plan - comprising both a discussion of current practices and the creation of a formal Standard Operating Procedure for the future - seems an obvious way to begin improving matters.

The prescribing of off-licence medicines should be an area of focus, both for the veterinary profession and the farming industry. Given dairy farming's inherent reliance on public trust in food safety practices (a fact highlighted by 2013's "horse-meat scandal") it is all too easy to imagine the negative impact of any exposé of any "horse-drug scandal" that the press may decide to publish. While the use of off-licence medicines is not illegal when prescribed and used according to the Cascade and where there are established MRLs, the lack of record keeping suggests mandatory maximum withdrawal times are not being adhered to. As argued by De Rosa and Trabalzi (2016) when discussing illegality in the Italian food trade, legality and illegality are "social constructs which are the product of institutional selection", as pithily summed up with their title: "Everybody does it". The current climate with regards to off-licence medicine use certainly seems to be one of 'don't ask, don't tell', and the lack of any formal recognition or measurement of the practice has consequences. As such, it is vitally important that such grey areas are tackled head-on and that meaningful, practical policies are introduced in order to both clarify the legal aspects of off-licence use and to formally measure the practice.

4.5.7 Future research

While this study highlights some important areas of interest, it is acknowledged that the sample size is small and was constrained by the requirements of the broader research project. This work therefore provides a rich source of pilot data which requires further investigation. A large, high-powered cross-sectional study of medicines stored on randomly selected UK dairy farms in different seasons would be required to provide a full and valid evidence base for policy decisions based upon storage practices to be made. Such a study would also be valuable in order to investigate the relationship between veterinary medicines stored on farm and those used, including the chronology of storage and use.

Resource availability: Investigating the contents of medicine cupboards

From such as study it might be possible to estimate PVM use behaviours based on PVM storage practices.

Much further research is needed on the subject of expired medicine use, in particular the effects of expiration on efficacy and any subsequent effects on risk of development of antimicrobial resistance. Equally it is important to focus on broached medicines and their use. The use of off-licence medicines in dairy cattle is currently very poorly measured and understood, including the adherence to extended Cascade withdrawal times. This seems surprising and a vital area for further work given the strict regulations and guidelines within which farmers and veterinary surgeon should be operating when treating food-producing animals, and the possible industry-wide detrimental effects of their likely widespread use being made public. While this area has not been ignored deliberately, continued inaction in the face of evidence will be difficult to justify. Equally, evidence of the extent of off-licence medicine use in agriculture is required urgently, and research in this area should be a focus for policy makers and funding bodies.

Chapter 5 Measuring prescription veterinary medicine use: a longitudinal method comparison study

5.1 *Abstract*

Antimicrobial use on dairy farms in the UK is measured nationally to satisfy European surveillance reporting requirements. However, measurement of non-antimicrobial veterinary medicine use is not currently undertaken at a national level. National antimicrobial use surveillance has recently begun to use veterinary sales data as a proxy for actual use; how well these data represent actual use, however, has not been validated. Other methods of recording use are available, such as the use of medicine waste bins and data from on-farm medicine treatment records. This longitudinal method comparison study compares these three measures of medicine use with a pre-determined gold standard measure of use.

Twenty-six dairy farms with a broad range of management systems, herd sizes and production goals were enrolled into the study in September 2016. A full prescription veterinary medicine (PVM) inventory was taken and a structured management survey was completed. Medicine waste bins were placed on farms and participants were asked to dispose of all used medicine packaging into these bins. Participants were asked to continue using and recording veterinary medicines in the usual way. PVM use was measured prospectively for a 12-month period through the medicine waste bins, with bins emptied and audited on a quarterly basis. At the end of the study, farm medicine records and veterinary sales data were obtained retrospectively for the study period, and medicine waste bins were removed.

Veterinary sales data was shown to be the best proxy for actual use when compared with a pre-determined 'gold standard'. Medicine waste bins showed reasonable agreement with the gold standard, whereas on-farm medicine records did not show agreement with the gold standard. Using veterinary sales data to measure injectable and intramammary antimicrobials showed the best agreement, whereas all methods showed poor agreement with the gold standard when measuring other types of antimicrobials, vaccines or all injectable products considered together.

5.2 Introduction

Antimicrobial use (AMU) is measured at a national level in the UK for the purposes of producing an annual report to satisfy the requirements of the European Medicines Agency's (EMA) European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, which began in 2010. In 2018, the EMA launched a project to stratify sales data of veterinary antimicrobials by animal species (European Medicines Agency, 2018). As previously described in Chapter 2, in the UK this report is published annually in the form of the Veterinary Antimicrobial Resistance and Sales Surveillance (VARSS) report, which has recently moved away from national production and import data towards using veterinary practice sales data to measure species-specific antimicrobial consumption. The data sources in the dairy sector are currently small, making up just over 33% of UK dairy cows in 2016 and 31% of UK dairy cows in 2017. While this move has served to increase the granularity of the data made available, the use of veterinary sales data as a proxy for use has never been validated in dairy cattle in the UK, and as such it has not been possible to estimate the representativeness of these data (Veterinary Medicines Directorate, 2017, Veterinary Medicines Directorate, 2018c).

While AMU has been monitored and reported systematically for many years, prescription veterinary medicine (PVM) use as a whole is not currently measured or monitored on a national level. Because of the potential usefulness of such data, individual veterinary practices, farms, agricultural consultancy and data management companies are increasingly attempting to collect and analyse PVM use to provide information on farm and veterinary economics and animal health, for example the farm benchmarking service provided by Kingshay (2018). The scattered nature of this endeavour involves many private businesses all striving to measure the same thing without communicating or agreeing on a measurement standard.

Previous research in Austria, Switzerland, Belgium and Germany have shown that veterinary sales data are superior to on-farm medicine records when measuring AMU (Ferner et al., 2014)(Pardon et al.,

2012, Menendez Gonzalez et al., 2010, Merle et al., 2012). These studies did not, however, include other forms of PVM or compare either of these methods with a gold standard. To the author's knowledge, there have been no published data on the usefulness of veterinary sales data as a proxy for measuring PVM use. The question of whether veterinary sales data can accurately reflect actual use is therefore both pertinent and largely unanswered, both specifically for measuring AMU and for measuring use of PVMs.

Dairy farmers in the UK are required by farm assurance schemes such as Red Tractor to keep medicine records for a minimum of 5 years. These requirements state that medicine purchases, treatments and disposal must be recorded. Medicine purchase records must contain information on "identity of medicine, quantity of medicine, date of purchase, name and address of supplier, batch number(s) and expiry date(s)". For medicine administration records, farmers must provide information on the "identity of medicine, quantity of medicine administered, batch number(s) or bottle number linked back to purchase records, identification of the animal or group of animals to which administered, number of animals treated, date of administration, date treatment finished, date when animal(s)/ milk becomes fit for human consumption, name of person administering medicine and reason for treatment." Additionally, farmers must provide medicine disposal records including data on "identity of medicine, date, quantity and route of disposal" (Red Tractor Assurance, 2017).

Given the detailed nature of the records that all Red Tractor-assured dairy farms (98% of all UK dairy farms are Red Tractor-assured) are required to keep, it would appear logical that to improve the granularity of antimicrobial and PVM use data, a move towards using on-farm records would be the next stage of progress (Responsible Use of Medicines in Agriculture Alliance, 2017). However, to the author's knowledge, there have been no studies of the accuracy or representativeness of on-farm records as a proxy for use. In fact, it is known that farmers see the keeping of medicine records as a

“tick-box-exercise” and of low priority when compared with the many other competing daily pressures of farming (Escobar, 2015).

The practicalities of using on-farm records has to date proven to be a barrier to the use of these data, given that farms may keep these records in multiple different formats (Mills et al., 2018). Some farms use computerised herd health management software with integrated medicine records, others use pre-prepared medicine record templates while others use less formalised systems written in day diaries or on scraps of paper. The Agriculture and Horticulture Development Board (AHDB) are currently developing and piloting a centralised, computer-based electronic medicine book system for collection of AMU data (eMB Cattle) with additional functionality allowing for the collection of full medicine records from cattle farmers. This system is based on the successful introduction of the electronic medicine book for the pig industry, eMB Pigs (AHDB Pork, 2018). While the successful introduction of eMB Cattle would greatly improve the granularity of AMU data available, and if the full medicine records used also include PVM use, there have not been any estimates of the validity of on-farm medicine records as a proxy for actual medicine use.

By comparing veterinary practice sales data with on-farm medicine records and a longitudinal on-farm medicine waste study, a measurement of agreement between the recording methods can be made. By assuming a gold standard measurement of actual PVM use, as described below, all three individual methods can be compared to the gold standard and an initial estimate of the validity of each method can be made.

5.3 *Methods*

5.3.1 Data handling

For each participating farm, an individual medicine workbook was created using Excel (Microsoft Office 365). Each workbook contained a spreadsheet listing every medicine on the VMD’s Product

Information Database (Veterinary Medicines Directorate, 2018b), along with columns for: the initial medicine cupboard inventory data, data from each quarterly medicine bin inventory, veterinary sales data and on-farm medicine book data. The workbooks also contained spreadsheets containing the structured questionnaire data, notes of any unlicensed or unlisted medicines found as well as any pertinent fieldnotes and reminders. Example screengrabs from these workbooks can be seen in Appendices 10 and 11.

5.3.2 Defining a “gold standard”

While it is possible to determine the agreement between different methods when measuring outcomes, in this case comparison is somewhat meaningless without knowing how closely any of these methods agrees with the true value of the outcome being measured. However, as with many clinical outcomes in healthcare research, knowing the “true” value is often all but impossible. In this case, a gold standard can be defined which is the closest to the truth that can reasonably be determined. While many people understand the term ‘gold standard’ to mean the true value, in medical statistics the gold standard can be described as “the diagnostic test or benchmark that is the best available under reasonable conditions” (Versi, 1992, imddle of page 187).

For this study, the gold standard was determined *a priori* in discussion with two veterinary epidemiologists (KR & FSV) and a data scientist (AD). When measuring actual medicine use on dairy farms, what we are ideally trying to measure is the amount of medicine administered to the cattle during a given time period. All the current methods for measuring this are proxies for use, that is they measure either what was recorded as being used, what was sold to the farm or what was discarded after use. These methods represent the most commonly used and logistically easy ways of estimating actual use. However, in order to measure actual use, it would be necessary to be present to record every administration of medicine for the entire study period, which is not practical.

From the three available methods, the potential for over- and under-estimation was discussed, and the possible ways of correcting these in order to approximate the 'true' value were explored as far as possible.

Veterinary sales data:

Overestimation – sold more during the time period than was actually used (i.e. medicines left in the cupboard at end of the study period). Wasted medicine not accounted for. Medicines ascribed to wrong species.

Underestimation – medicines are used which were purchased before the study period, medicines purchased or obtained from sources other than veterinary practice. Medicine ascribed to wrong species.

On farm medicine records:

Overestimation – Farmer records more medicines being used than actually administered (e.g. records all dry cow treatments as x4 tubes where some cattle have three teats).

Underestimation – Farmer forgets or neglects to record treatments.

Medicine waste bins:

Overestimation – Farmer discards medicines packaging into bins which were actually used before study period (i.e. finds a stash of empty medicine bottles and uses the bin to dispose of them).

Underestimation – Farmer forgets to use the bin or only uses the bin for some treatments and not others or chooses to dispose of medicines packaging elsewhere, medicines used by the veterinary surgeon and not left on the farm.

It was determined that the method best suited to determine the gold standard and where the potentials for over- and under-estimation could be corrected for the most easily was veterinary sales

data, as this did not rely on farmer compliance or memory. It was determined that the potential for a 'time-lag' in veterinary sales data could be corrected by taking a full PVM inventory of the farm on the first and last day of the study in order to correct for the potential for use of medicines that were already in stock at the start of the study as well as for medicines that were not used and remained in stock at the end of the study.

'Gold Standard' = (initial inventory + veterinary sales data) - end inventory

This gold standard was still open to underestimation where farms sourced medicines from sources other than their veterinary surgeon. This was corrected for as far as practicable by enquiring whether medicines were ever sourced from elsewhere and checking veterinary labels during bin audits and medicine cupboard inventories.

5.3.3 Medicine waste bins

The research methods for data collection using medicine waste bins are described in detail in Chapter 3, Section 3.5.3 along with a description of piloting of the method in Section 3.5.6. To recap briefly, medicine waste bins were placed on each participating farm at the initial inventory visit in the size, number and location of the farmers' choice. Farmers were instructed how to use the bins and signage (Appendix 7) to remind them was placed strategically around the farm. All farms were then visited quarterly and the contents of the bins were transferred into individually labelled transport containers and transported back to the research area at the University of Bristol's (UoB) Langford Campus.

Once each farm's quarterly bin contents were collected, these bins were individually analysed in a dedicated research space at UoB Langford Campus. This research space consisted of a large concrete feed manger where the contents of each individual bin was decanted for counting. From here, these contents were sorted using large plastic trays, and analysed. Information about the contents were entered into pre-prepared spreadsheets, one per participating farm. The data collected from the bin

inventories comprised of the medicine identity, pack size, quantity of packs, any waste medicine remaining within each pack, the expiry date and the presence of a veterinary dispensing label. These data were entered into a dedicated spreadsheet for each participating farm using Excel (Microsoft Office 365). Once the contents of the medicine waste bins had been recorded, the bins were sealed and disposed of as clinical waste.

Protective equipment was necessary during these medicine bin inventories due to the presence of broken glass, open medicine packaging and used, unsheathed needles. The quantity of waste medicines present in each farm's bins varied, with some farms providing several 120 L bins worth of used PVM and others providing a handful of used bottles and intramammary tubes per quarter.

During the third quarterly bin inventory, a veterinary undergraduate who was undertaking a research placement within the AMR Force research group was present and conducted a second inventory of each bin's contents for 15 farms. The data collected by the undergraduate was compared with the data collected during the study inventory in order to validate the counting method. It was found that the percentage difference between both counts (total number of packs present) for each of the 15 farms' bins was less than 3% (median number of items per bin 342, range 64 - 697) indicating that the inventory data collected in this project was relatively robust.

Where medicines were found to have expired before the first day of the quarter of data collection being tallied, these were classified as expired medicines. Where PVM were found to have expired during the period for which the count was taking place, the benefit of the doubt was given that the medicine was used before the expiration and the medicine was not classified as having expired. Where medicine packages had lost all identifying feature (the label had perished completely), these were disregarded although such instances were rare (n=14). Any waste medicine remaining within each pack was estimated by eye to the nearest 10% (i.e. for a 100 ml bottle of injectable PVM, any remaining product was estimated to the nearest 10 ml).

Where possible, the final bin collection took place on the 12-month anniversary (i.e. Day 365) of the date the bins were first placed on each farm. However, in instances where this was not possible, bins were collected within 3 days of the 12-month anniversary.

5.3.4 Veterinary sales data

Consent for the collection of veterinary sales data from each participating farm's veterinary practice was obtained during the initial farm visit. Veterinary sales data for each participating farm were requested once from their veterinary practices' administration team at the end of the 12-month medicine waste bin study. A copy of the consent form was included in the request. A research associate (GG) from the AMR Force research group contacted each of the nine veterinary practices requesting veterinary sales data for the entire time period of the study. These data were supplied by email in various formats, ranging from Word (Microsoft Office 365) documents, .pdf (Adobe Reader XI) documents, scanned practice management software printouts and Excel (Microsoft Office 365) spreadsheets.

Once these data had been collected, total quantities of units sold for each different medicine were tallied and entered into the respective farm's medicine spreadsheet. Veterinary sales which were administered by the veterinary surgeon (rather than dispensed to the farmer) were identified through identifying visit chronology and disregarded. Participating farmers had confirmed that those medicines which were administered by visiting veterinary surgeons from non-farm stock would usually not end up in the bin due to a dose being drawn from a multi-dose vial, and for it to be common practice for farm animal veterinary surgeons to dispose of their own medicine waste at the end of a visit. Veterinary administrations were also reported to be rarely, if ever, recorded in the on-farm medicine book; instead veterinary invoices were kept separately.

5.3.5 On-farm medicine records

On-farm medicine records were collected on or after the final day of the medicine waste bin study. These records took various forms ranging from dedicated computer software to farmer-created spreadsheets, handwritten medicine books or simply entries in the day diary. Where records were computerised, a copy was downloaded onto a USB stick or a print-out was made for the time-period required. On one occasion neither method was possible and therefore photographs of the computer screen were taken. Where medicine records were handwritten, photographs of each page of the medicine record book or day diary were taken consecutively, covering the 12-month period of interest.

Computerised data were then collated, with the total volume recorded for each medicine over the entire 12-month period tallied and entered into the respective farm's medicine spreadsheet. Photographs of hand-written medicine records were analysed temporally for the 12-month period and the total volume for each medicine was similarly tallied and entered into that farm's medicine spreadsheet.

5.3.6 Classification of PVM

Prescription veterinary medicines were classified according to their Veterinary Medicines Directorate (2018b) classification for analysis as follows:

- **Injectable antimicrobials:** all antimicrobial POM-V products of injectable form. Combination products containing an antimicrobial as one of the active ingredients (e.g. florfenicol & flunixin) were classified as antimicrobials. Where an antimicrobial presented as a powder for reconstitution this was classified as an injectable antimicrobial and it was assumed that the reconstituted product would be made up to the correct volume as per the manufacturer's datasheet.

- Intramammary antimicrobials: all antimicrobial products of intramammary form.
- Other antimicrobials: all antimicrobials that do not fit into the above two categories. This included ocular preparations, tablets and boluses, powders used as footbaths but did not include monensin used to prevent ketosis.
- All injectables: All PVM presented in injectable form, including antimicrobials, non-steroidal anti-inflammatories, hormone preparations, etc., but not including vaccines.
- Teat sealants: all mechanical teat sealants.
- Vaccines: all vaccine products, whether injectable or intranasal.

5.4 *Data analysis*

Data was collated, cleaned and validated in Excel (Microsoft Office 365). Once the full 12 months of data had been prepared for each of the 26 participating farms, the approach to data analysis was decided upon after critical appraisal of the method agreement literature by the author and developed with the help of an experienced epidemiologist from the Bristol Veterinary School (FSV), who also conducted the analysis using R software (R Core Team, 2012). Four different approaches were used to analyse method agreement for the following combinations:

- **Vet sales vs. Gold standard**
- **Medicine bin vs. Gold standard**
- **Farm records vs. Gold standard**

Sample size estimation for reliability calculations was based on two observations per subject because all three methods of measurement were compared separately with the gold standard. An expected reliability value of 0.9 and an acceptable lower limit of reliability width of the 95% confidence interval of 0.7 was used, which gave a sample size requirement of 18 farms. This was then corrected to 23

farms based on an expected drop-out rate of 20% (Walter et al., 1998). This was deemed to be acceptable as 27 farms were enrolled onto the original project, and complete data was collected for 26 farms.

Analysis was conducted separately for the seven different types of PVM listed above. Initially, one-way repeated measures ANOVAs were used to investigate whether there was a systematic difference between the mean medicine use measured by four different recording methods in a farm-level sample (Table 5:1). “Medicine use” was the dependent variable, whilst the independent variable was “recording method”. Prior to analysis, the normality of the dependent variable for each level of the independent variable was determined by visual examination of quantile–quantile plots and confirmed by a Shapiro–Wilk normality test ($p > 0.05$; results not shown). Where the normality assumption was not met after data transformation, a non-parametric Quade test was conducted to assess whether the distribution of values for each recording method were equal. The assumption of sphericity was tested using Mauchly’s Test of Sphericity. Where sphericity was violated, we used the Greenhouse-Geisser correction to make an adjustment to the degrees of freedom of the repeated-measures ANOVA. Where significant results were found, post-hoc tests for differences between means were adjusted for multiple comparisons using Tukey’s test. When a Quade test was conducted, post-hoc tests for differences between distribution of values were adjusted for multiple comparisons following Holm’s method. If the difference between means for any pair of recording methods being compared was non-significant (i.e. there was no evidence of a systematic effect), the following two approaches were used to measure levels of agreement and reliability between such recording methods.

Table 5:1 Tests and transformations used to investigate whether there was a systematic difference between the mean medicine use measured by three different recording methods when compared with a gold standard measure in a farm-level sample.

Medicine type	Test	Transformation used for modelling
<i>Injectable antimicrobial</i>	Repeated measures ANOVA	$\log_{10}(x + 100)$
<i>Intramammary antimicrobial</i>	Repeated measures ANOVA	$\log(x + 10)$
<i>Other antimicrobial</i>	Non-parametric one-way ANOVA	None
<i>All injectables</i>	Repeated measures ANOVA	$\log(x + 250)$
<i>Vaccines</i>	Non-parametric one-way ANOVA	None
<i>Teat sealant</i>	Non-parametric one-way ANOVA	None

The reliability between each pair of methods was measured using the intraclass correlation coefficient (ICC) (Watson and Petrie, 2010). The ICC takes a value from 0 (implying no agreement) to 1 (perfect agreement). Values less than 0.5 are indicative of poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability, and values greater than 0.90 indicate excellent reliability. ICC estimates and their 95% confident intervals were calculated based on a single-rating, absolute-agreement, 2-way mixed-effects model (Koo and Li, 2016). The normality of the medicine use recorded by each method was determined as detailed above. Where the normality assumption was violated, a data transformation was applied.

In order to measure the agreement between each pair of methods (i.e. the three recording methods against the gold standard), the Bland-Altman method was used (Bland and Altman, 1999). This method calculates the 'bias' and 95% limits of agreement between two methods, where the bias is the mean difference between the two methods. The 95% limits show the range where 95% of the differences between the two methods would be expected to lie. While the 95% limits show visually how well two methods of measurement agree, this quality judgement of this agreement depends on clinical context. Additionally, while the ICC shows the level of reliability between each pair of methods, this does not take into account the clinical context to tell us whether the level of agreement is acceptable. Therefore, a clinically relevant level of agreement should be used when evaluating method

comparison studies. In this case, it was decided *a priori* in discussions between GR, KR and DB in this study that if the 95% limits of agreement were within 30% of the mean total for the gold standard, this would equate to 'reasonable agreement'; if they were within 20% of the mean total for the gold standard this would represent 'good agreement'; and if they lay within 10% of the mean total for the gold standard, this would represent 'excellent agreement'. This was based on the decision that a 30% over- or under-estimation of actual use would be acceptable as a proxy of AMU, but less than 20% over- or underestimation would be ideal. We used the Bland-Altman plot and Shapiro-Wilk normality test to check the assumptions of the method. The Bland-Altman plot was also used to detect outliers and the influence of large outliers was evaluated by recalculating the limits of agreement when these outliers were excluded (Watson and Petrie, 2010). Because for this dataset it was impossible to interpret whether outliers were due to data error or due to between-farm variation, data were analysed both including and excluding the outliers as described, and both sets of analyses presented in order to ensure completeness for the reader. In the analysis and interpretation of the data, only data including all outliers were used. Where the agreement between recording methods varied with the quantity being measured, we attempted to resolve this difficulty by analysing the logarithm of the measurement rather than the measurement itself. For data sets for which log transformation does not remove the relationship between the differences and the size of the measurement, a Bland-Altman plot was used to help in comparing the methods.

The method agreement analyses used in this study were designed to measure the agreement between different methods of recording the same variable. That means that inherent within the methodology of the analysis is a measurement of the random or systematic measurement errors that occur. While the gold standard used in this chapter is related to one of the measurements (veterinary sales data), the analysis essentially showed that, although there is no systematic difference between the two results, there nevertheless exists a difference. The analysis provided a measure of the difference seen

between the gold standard and each method, including the method upon which the gold standard was based. Essentially, therefore, the analysis proved that the gold standard and the veterinary sales data did not produce the same result but did produce results which agreed well both statistically and clinically (as did the medicine waste bins in some circumstances). The Bland-Altman diagram provided a display of the differences between the pairs of readings. If the gold standard and the veterinary sales data were essentially the same measure, the Bland-Altman diagrams would show perfect agreement (i.e. a straight line centred at zero). In fact, they did not show that the measures obtained by veterinary sales data were different from those obtained by using the gold standard, although agreement was good. This can be explained as described in Section 5.3.2: veterinary sales data when combined with a pre- and post-audit inventory provided a different measure to veterinary sales data alone because the pre- and post-audit inventories provide additional use data not incorporated into the veterinary sales data alone. These measures were of course related and would be expected to exhibit correlation as they are different measures of the same variable (Watson and Petrie, 2010).

5.5 Results and discussion

Measuring on-farm PVM use can be conducted using many different methods, as described in the introduction to this chapter. This study has compared the three most common methods for measuring PVM use against a gold standard that was agreed *a priori*. PVM use was subdivided into the different medicine types that were deemed clinically important: injectable antimicrobials, intramammary antimicrobials, other antimicrobials, all injectables, teat sealants and vaccines. This categorisation of the medicine types was agreed in discussion with clinicians and academics during farm animal clinical discussion meetings. Descriptive statistics for the quantities and units of measurement of these different medicine types recorded by the three different methods are presented in Table 5:2. As the distribution was not normal for any of the medicine types recorded, median values are reported along with the range.

Table 5.2: Descriptive statistics of the quantities of different medicine types recorded across all participating farms over the 12 month period (n=26), by the three different recording methods.

		Recording method	Medicine type					
			Injectable antimicrobial (ml)	Intramammary antimicrobial (tube)	Other antimicrobial (individual unit)	All injectables (ml)	Teat Sealant (tube)	Vaccines (dose)
Quantity across all farms over 12 months (n = 26)	Total use	Vet sales	192879.5	25872	25252	242020	12803	10740
		Medicine book	132341	22619	770	160987.5	8359	1364
		Waste bin	169960	21545	605	218283	7504	12130
	Median use	Vet sales	5500	679	25	7755	480	250
		Medicine book	4308.75	577.5	0	5805.25	20	0
		Waste bin	5505	591.5	2.5	7392.5	161	250
	Range	Vet sales	1300 - 21910	120 – 3163	0 – 23314	1400 – 27360	0 – 1500	0 – 1600
		Medicine book	0 - 20019	112 – 2800	0 – 441	0 – 23236	0 – 1436	0 – 569
		Waste bin	900 - 18740	140 - 2463	0 - 605	1000 - 24904	0 – 1390	0 - 3800

5.5.1 Type of PVM measured

5.5.1.1 Injectable antimicrobials

The mean quantity of injectable antimicrobials measured was significantly different between at least two recording methods ($F_{3,75} = 12.91$, $p < 0.001$, p-value after using Greenhouse-Geisser correction: $p(\text{GGe}) < 0.001$). The mean quantity of injectable antimicrobials measured by the gold standard method was not significantly different to the mean amount measured using veterinary sales ($p = 0.995$) or waste bin ($p = 0.822$), whilst it was significantly different to the mean amount measured using the medicine book ($p < 0.001$).

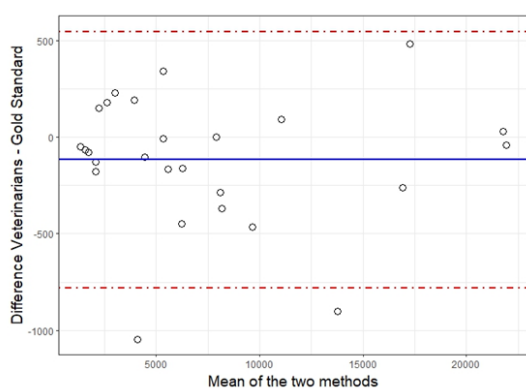


Figure 5-1. Bland-Altman plot comparing veterinary sales data with gold standard data for injectable antimicrobials in total ml¹

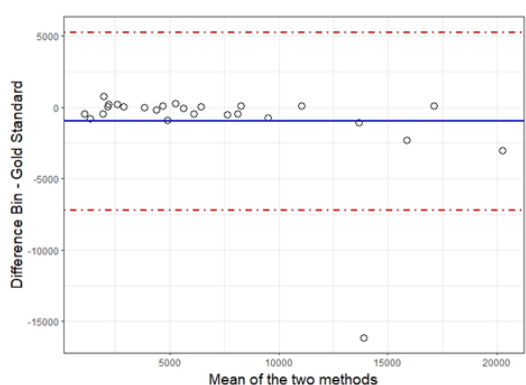


Figure 5-2. Bland-Altman plot comparing medicine waste bin data with gold standard data for injectable antimicrobials in total ml¹.

For 95% of farms, a measurement of injectable antimicrobials by veterinary sales data would be between 782.3 ml less and 546.1 ml greater than a measurement by the gold standard method (Table 5:3). The Bland-Altman plot for veterinary sales vs. gold standard is shown in Figure 5-1. The ICC of

¹ The y-axis represents the difference between the two named methods, and the x-axis represents the mean of the two methods. Dots represent the mean difference between the methods for each participating farm. The blue line represents the mean difference between methods across all farms and the red hashed line represents the 95% limits of agreement.

injectable antimicrobials measured by veterinary sales compared with the gold standard is presented in Table 5:4 and showed excellent reliability.

Because the limits of agreement cross zero, this means that veterinary sales data can under- or overestimate actual use of injectable antimicrobials. This equates to a difference of 14% underestimation to 10% overestimation for 95% of farms when compared with the median total per farm. As discussed in the Data Analysis section, the clinical interpretation of agreement is arguably the most important when comparing methods of measurement. Using the agreed clinical agreement criteria, this represents good agreement (within 20%) between veterinary sales data and actual use for injectable antimicrobials (Table 5:5). For injectable antimicrobials, veterinary sales data overestimated use by a mean of 118 ml, which is the equivalent of just over one 100 ml bottle of injectable antimicrobial per farm over a 12-month period.

Table 5:3 Bland-Altman Plot statistics for all comparison of medicine use recording methods.

*one outlier removed ** two outliers removed ***transformed *** transformed and one outlier removed

Medicine Group	Comparison	Mean difference	SD	95% limits of agreement	% farms within 95% limits	95% CI of the mean difference
Injectable antimicrobials	Vet sales vs. gold standard	-118.11	338.89	-782.34 to 546.11	92.3	-255.03 to 18.80
	Waste bin vs. gold standard	-999.63	3184.89	-7242.01 to 5242.75	96.1	-2286.33 to 287.06
	Waste bin vs. gold standard**	-285.02	610.91	-1482.4 to 912.36	95.8	-543.15 to -26.89
Intramammary antimicrobials	Vet sales vs. gold standard	-0.519	75.30	-148.10 to 147.07	92.3	-30.94 to 29.90
	Waste bin vs. gold standard***	-0.13	0.43	-0.98 to 0.72	96.2	-1.29 to 0.68
	Waste bin vs. gold standard****	0.05	0.43	0.23 to 0.14	96.2	0.09 to 0.68
Other antimicrobials	Vet sales vs. gold standard	-5.38	31.20	-66.54 to 55.77	92.3	-17.99 to 7.22
All injectable products	Vet sales vs. gold standard	-1090.85	3999.47	-8929.82 to 6748.12	96.2	-2706.63 to 524.94
	Waste bin vs gold standard	-912.96	4059.05	-8868.69 to 7042.77	96.2	-255.81 to 726.89
Vaccines	Vet sales vs. gold standard	-68.00	257.64	-572.98 to 436.98	92.3	-172.09 to 36.09
	Waste bin vs. gold standard	53.46	723.99	-1365.57 to 1472.49	96.2	-239.03 to 345.95
Teat sealant	Vet sales vs gold standard	8.5	97.08	-181.78 to 198.78	96.2	-30.72 to 47.72
	Vet sales vs. gold standard*	26.04	38.54	-49.50 to 101.58	100	10.16 to 41.92

Formatted: German (Germany)

Formatted: German (Germany)

Formatted: German (Germany)

Formatted: German (Germany)

Formatted: German (Germany)

Formatted: German (Germany)

The medicine waste bin method may give values between 5242.7 ml of injectable antimicrobial above the gold standard method to 7242.0 ml below gold standard (Table 5:3). However, this result needs to be interpreted with caution because the differences between the methods were not normally distributed even after log transformation. In such cases, the estimated limits of agreement tended to be too far apart rather than too close and should not inadvertently lead to the acceptance of poor methods of measurement. The Bland-Altman plot revealed two large outliers (Figure 5-2). Removing these outliers improved the closeness of the distribution to normality but did not solve the problem. These two outliers also had a big impact on the limits of agreement. After excluding them, the mean difference became -285.0 (i.e. on average the medicine waste bin measured 285.0 ml less than the gold standard); the 95% limits of agreement were 912.4 ml above the gold standard and 1428.4 ml below it.

Based on the ICC results as seen in Table 5:4, the reliability of injectable antimicrobials measured by waste bin compared with the gold standard was good to excellent. The clinical interpretation as shown in Table 5:5 represented moderate to good agreement.

Table 5:54. Intraclass correlation coefficients and statistical interpretation of reliability comparing veterinary sales and medicine waste bin data with the gold standard for the different medicine types.² Statistical interpretation is based on:

ICC < 0.5: poor reliability

0.5 >= ICC <= 0.75: moderate reliability

0.75 > ICC <= 0.9: good reliability

ICC > 0.9: excellent reliability

Method comparison	Medicine type	Intraclass Correlation Coefficient (ICC)	95% Confidence intervals (p<0.01)	Statistical Interpretation of reliability
Vet sales Vs. gold standard	Injectable antimicrobial	0.997	0.992 – 0.999	Excellent
	Intramammary antimicrobial	0.991	0.981 – 0.996	Excellent
	All injectables	0.996	0.990 – 0.998	Excellent
	Other antimicrobials	0.727	0.481 – 0.867	Poor to good
	Vaccines	0.878	0.749 – 0.943	Moderate to excellent
	Teat sealants	0.976	0.947 – 0.989	Excellent
Waste bin Vs. gold standard	Injectable antimicrobial	0.926	0.843-0.966	Good to excellent
	Intramammary antimicrobial	0.789	0.586 – 0.899	Moderate to good
	All injectables	0.900	0.790 – 0.954	Good to excellent
	Other antimicrobials	N/A ¹		
	Vaccines	0.927	0.844 – 0.966	Good to excellent
	Teat sealants	N/A ¹		

Formatted: German (Germany)

² Medicine types and recording methods that were shown to be systematically different to the gold standard by repeated measures one-way ANOVA were not included for further analysis and are not presented in this table.

Table 5:5. Clinical interpretation of limits of agreement for each medicine type and recording method, when compared with the median total quantity for that medicine on each farm (n=27) as recorded by the gold standard.³ Based on differences of:

>30% = poor agreement,

21-30% = reasonable agreement,

11-20% = good agreement and

0-10% = excellent agreement

Recording method	Medicine type	Difference from gold standard (%)	Clinical interpretation
Veterinary sales data	Injectable antimicrobial	-14 to 10	Good
	Intramammary antimicrobial	-22 to 21	Moderate
	Other antimicrobial	-148 to 124	Poor
	All injectables	-113 to 85	Poor
	Vaccines	-205 to 156	Poor
	Teat sealant	-12 to 25	Moderate to good
Medicine waste bins	Injectable antimicrobial	-27 to 17	Moderate to good
	Intramammary antimicrobial	-63 to 106	Poor
	Other antimicrobial	N/A ²	
	All injectables	-112 to 89	Poor
	Vaccines	-488 to 526	Poor
	Teat sealant	N/A ²	

5.5.1.2 Intramammary antimicrobials

The mean quantity of intramammary antimicrobials measured was significantly different between at least two recording methods ($F_{3,75} = 3.268$, $p < 0.03$, $p(\text{GGe}) < 0.0497$). The mean quantity of intramammary antimicrobials measured by the gold standard method was not significantly different to the mean amount measured using veterinary sales ($p = 0.999$) or waste bin ($p = 0.355$), whilst it was significantly different to the mean amount measured using the medicine book ($p = 0.043$).

³ Medicine types and recording methods that were shown to be systematically different to the gold standard by repeated measures one-way ANOVA were not included for further analysis and are not presented in this table.

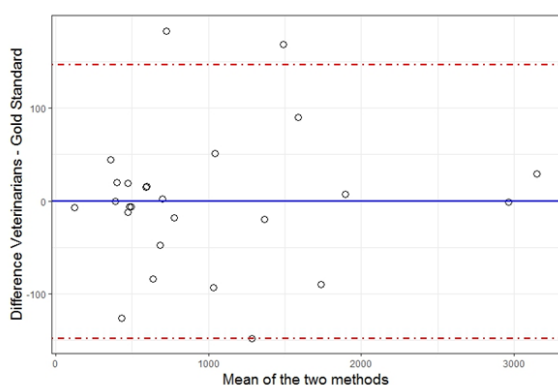


Figure 5-3. Bland-Altman plot comparing veterinary sales data with gold standard data for intramammary antimicrobials in total number of tubes⁴.

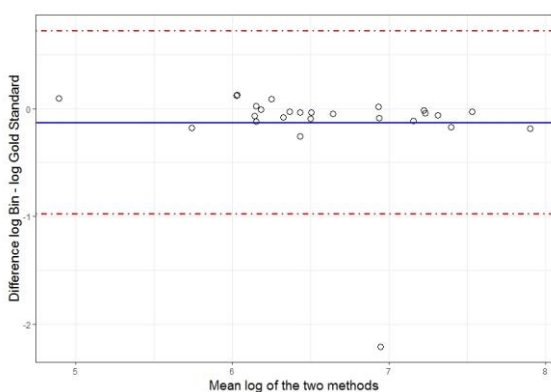


Figure 5-4: . Bland-Altman plot comparing transformed medicine waste bin data with gold standard data for intramammary antimicrobials in total number of tubes.⁴

For 95% of farms, a measurement of intramammary antimicrobials by veterinary sales data would be between -148.10 tubes less and 147.07 tubes greater than a measurement by the gold standard

⁴ The y-axis represents the difference between the two named methods, and the x-axis represents the mean of the two methods. Dots represent the mean difference between the methods for each participating farm. The blue line represents the mean difference between methods across all farms and the red hashed line represents the 95% limits of agreement.

method. The Bland-Altman plot for veterinary sales vs. gold standard is shown in Figure 5-3 and statistics are reported in Table 5:3. The ICC of intramammary antimicrobials measured by veterinary sales compared with the gold standard is presented in Table 5:4 and showed excellent reliability. The clinical interpretation of the difference between the limits of agreement and the median gold standard use per farm represented moderate agreement (Table 5:5).

The differences between waste bin measures and the gold standard were not normally distributed. A log transformation slightly improved the closeness of the distribution to normality. The Bland-Altman plot and statistics for log transformed data are shown in Figure 5-4 and Table 5:3, respectively. The limits of agreement derived from log-transformed data were back-transformed (antilog) to give limits for the ratio of the actual measurements (Bland and Altman, 1986). The antilogs of these 95% limits of agreement were 0.37 and 2.06. These limits indicate that for 95% of farms the quantity of intramammary antimicrobials recorded by the waste bin method will be between 0.37 and 2.06 times the quantity recorded by the gold standard. Thus, the waste bin measurement may differ from the gold standard measurement by 63% below to 106% above the gold standard measurement. The Bland-Altman plot revealed a very large outlier (Figure 5-4). Removing this outlier solved the violation of normality and had a big impact on the limits of agreement (Table 5:3). After excluding it, the waste bin measurement differed from the gold standard measurement by 21% below to 15% above. As with injectable antimicrobials, when comparing the waste bin method to the gold standard, the differences were not normally distributed, which could lead to an overestimated size of the limits of agreement. Based on the clinical agreement measures defined in the Data Analysis section this equates to a moderate agreement. However, because the removal of outliers cannot be fully justified unless the outlier is considered to be incorrect, the data presented in Table 5:5 for clinical agreement is that of the full dataset, representing poor clinical agreement. Based on the ICC results presented in Table 5:4,

the reliability of intramammary antimicrobials measured by waste bins compared with the gold standard was moderate to good (0.789, 95% CI = 0.586 – 0.899, $p < 0.01$).

For intramammary antimicrobials, veterinary sales data estimated use to within one tube of the gold standard. The 95% limits of agreement again crossed zero (-148.1 to 147.07); as above, this illustrates that veterinary sales have the potential to over- or underestimate actual use of intramammary antimicrobials.

Injectable and intramammary antimicrobials may be considered the most important PVM from a use surveillance point of view due to the current ESVAC requirements to collate and publish annual data on AMU (European Medicines Agency, 2017), and indeed these are the antimicrobials most commonly used (Veterinary Medicines Directorate, 2018c). In this study, the results for these two types of PVM were relatively straightforward and suggest that using veterinary sales data is a reliable way of estimating use, although sales data tends to underestimate use and can both under- or overestimate use. With an increasing number of years of data from veterinary sales, it is likely that the degree of over- or underestimation would decrease, and veterinary sales data would more closely approximate actual use over a longer time period. For example, medicines being used from or stored in the medicine cupboard would be more likely to be used over a longer time period. Medicine waste bins showed poor clinical agreement, although removal of the one outlier did improve this to reasonable agreement. Further studies with a greater sample size may help to show whether this outlier was incorrect or not.

5.5.1.3 Other antimicrobials

‘Other’ antimicrobials are also an important component of AMU surveillance, but the picture is complicated by the various different units of measurements, depending on what form the ‘other’ antimicrobial took. For ophthalmic ointments, measurement was on a per tube basis. Antimicrobials in powder form were measured per sachet, and in tablet or bolus form were measured per packet.

This makes it inherently difficult to compare the figures for 'other antimicrobials' with those for injectable or intramammary antimicrobials as the potential for over- or underestimation is likely to vary between these different presentations. However, it was decided that measuring for each different formulation was not possible owing to the sheer volume of data analysis required. Additionally, 'other antimicrobials' make up a small proportion of overall antimicrobial use, with injectable and intramammary antimicrobials known to be the most commonly used antimicrobials (Veterinary Medicines Directorate, 2018c, Hyde et al., 2017). Despite this, as it is valuable to be aware of the likely degree of over- or underestimation of these particular antimicrobials when measuring on-farm AMU, their inclusion as a group is justified.

There was a significant difference in the measurement of other antimicrobials across recording methods ($F_{3,75} = 16.22$, $p = < 0.001$). The quantities of other antimicrobials measured by the gold standard method were not significantly different to the quantities measured using veterinary sales ($p = 0.467$), whilst these quantities were significantly different to the quantities measured using the waste bin ($p < 0.001$) and the medicine book ($p < 0.001$).

Veterinary sales data may give values between -66.54 units fewer to 55.77 units greater of 'other' antimicrobial than the gold standard method (Table 5:3). However, this result needs to be interpreted with caution because the differences between both methods were not normally distributed even after log transformation. As previously stated, the estimated limits of agreement tend to be too far apart rather than too close and should not inadvertently lead to the acceptance of poor methods of measurement. Based on the ICC results shown in Table 5:4, the reliability of other antimicrobials measured by veterinary sales compared with the gold standard was poor to good (0.727, 95% CI = 0.481 – 0.867, $p < 0.01$). Based on the clinical interpretation as shown in Table 5:5, agreement was poor.

5.5.1.4 All injectables

The mean quantity of all injectable antimicrobials measured was significantly different between at least two recording methods ($F_{3,75} = 15.41$, $p < 0.001$, $p(\text{GGe}) < 0.01$). The mean amount of injectable product measured by the gold standard method was not significantly different from the mean amount measured using veterinary sales ($p = 0.995$) or waste bins ($p = 0.829$), whilst it was significantly different to the mean amount measured using the medicine book ($p < 0.001$).

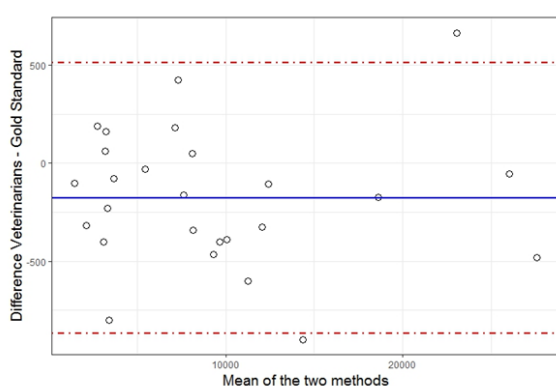


Figure 5-5. Bland-Altman plot comparing veterinary sales data with gold standard data for all injectable prescription veterinary medicines in total ml⁵.

⁵ The y-axis represents the difference between the two named methods, and the x-axis represents the mean of the two methods. Dots represent the mean difference between the methods for each participating farm. The blue line represents the mean difference between methods across all farms and the red hashed line represents the 95% limits of agreement.

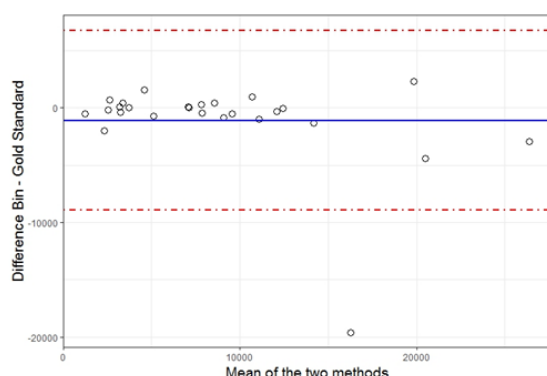


Figure 5-6. Bland-Altman plot comparing medicine waste bin data with gold standard data for all injectable prescription veterinary medicines in total ml.⁶

For 95% of farms, a measurement of injectable antimicrobials by veterinary sales data would be between -8929.82 ml less and 6748.12 ml greater than a measurement by the gold standard method (Table 5:3). The Bland-Altman plot for veterinary sales vs. gold standard is shown in Figure 5-5. The ICC of all injectable products measured by veterinary sales compared with the gold standard is reported in Table 5:4 and showed excellent reliability. However, the clinical interpretation, as presented in Table 5:5, represented poor agreement.

For medicine waste bins, 95% of farms would have a measure of all injectables between 8868.69 ml less and 7042.77 ml greater than a measurement by the gold standard method (Table 5:3). The ICC of all injectable products measured by medicine waste bins compared with the gold standard is reported in Table 5:4 and showed good to excellent reliability. However, the clinical interpretation as seen in Table 5:5 showed poor agreement.

⁶ The y-axis represents the difference between the two named methods, and the x-axis represents the mean of the two methods. Dots represent the mean difference between the methods for each participating farm. The blue line represents the mean difference between methods across all farms and the red hashed line represents the 95% limits of agreement.

5.5.1.5 Vaccines

There was a significant difference in vaccines measured among recording methods ($F_{3,75} = 17.43$, $p = < 0.001$). The quantities of vaccines measured by the gold standard method were not significantly different to the quantities measured using veterinary sales ($p = 0.590$), or the quantities measured using the medicine waste bins ($p = 0.170$) whilst these quantities were significantly different to the quantities measured using the medicine book ($p < 0.001$).

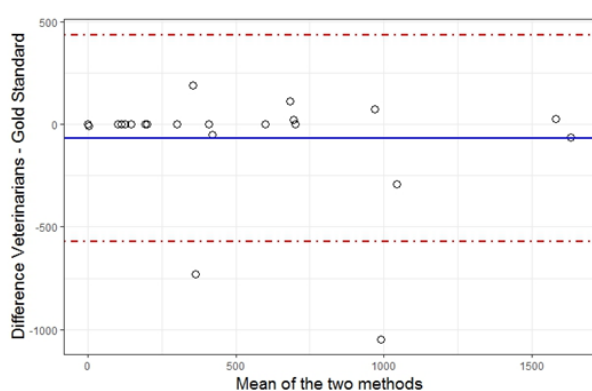


Figure 5-7. Bland-Altman plot comparing veterinary sales data with gold standard data for vaccines in total number of doses.⁷..

⁷ The y-axis represents the difference between the two named methods, and the x-axis represents the mean of the two methods. Dots represent the mean difference between the methods for each participating farm. The blue line represents the mean difference between methods across all farms and the red hashed line represents the 95% limits of agreement

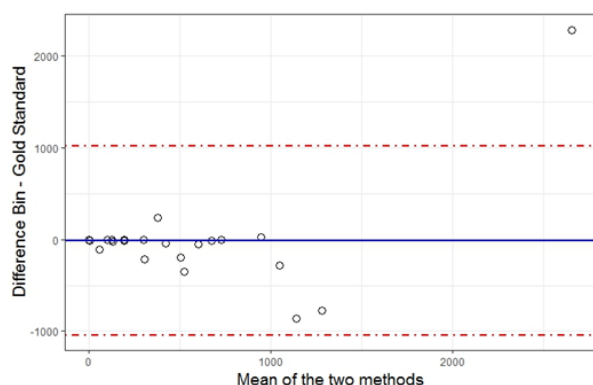


Figure 5-8. Bland-Altman plot comparing medicine waste bin data with gold standard data for vaccines in total number of doses.⁸

The Bland-Altman plot for veterinary sales vs. gold standard is shown in Figure 5-7 and for waste bin vs. gold standard is shown in Figure 5-8; statistics are reported in Table 5:3.

Veterinary sales data may give values between 572.98 doses of vaccine below the gold standard method to 436.98 doses above it. Medicine waste bins may give values 1365.57 doses below the gold standard method to 1472.49 doses above it (Table 5:3). However, these results need to be interpreted with caution because the differences between both methods were not normally distributed even after log transformation. In such cases, the estimated limits of agreement tend to be too far apart rather than too close, and should not inadvertently lead to the acceptance of poor methods of measurement.

The ICC of vaccines measured by veterinary sales data compared with the gold standard is presented in Table 5:4 and showed moderate to excellent reliability. The ICC of vaccines measured by medicine waste bins compared with the gold standard is also presented in Table 5:5 and showed good to excellent reliability. The clinical interpretation of both veterinary sales data and medicine waste bins'

⁸ The y-axis represents the difference between the two named methods, and the x-axis represents the mean of the two methods. Dots represent the mean difference between the methods for each participating farm. The blue line represents the mean difference between methods across all farms and the red hashed line represents the 95% limits of agreement

agreement with the median gold standard measurement of use on each farm represented poor reliability (Table 5:5).

When measuring vaccine use, there is currently no national recording or surveillance system, therefore data on use of these veterinary medicines is largely unavailable. In addition, not all vaccines are POM-V. Private veterinary practices have created their own PVM recording and benchmarking systems, although the ownership and sharing of this data is often contentious and validation of the data is difficult. However, RUMA's approach to encouraging the responsible use of medicines includes the promotion of preventive medicine and alternatives to antimicrobials (Responsible Use of Medicines in Agriculture Alliance, 2017). An increasing use of vaccines should lower disease burden and reduce the need for antimicrobials. The inclusion of these other veterinary medicines in this analysis provides a basis for stakeholders when deciding whether to begin surveillance of vaccine use in the future.

5.5.1.6 Teat sealants

There was a significant difference in teat sealants measured among recording methods ($F_{3,75} = 9.25$, $p = < 0.001$). The quantities of teat sealants measured by the gold standard method were not significantly different to the quantities measured using veterinary sales ($p = 0.193$), whilst they were significantly different to the quantities measured using the waste bins ($p < 0.05$) and the medicine books ($p < 0.05$).

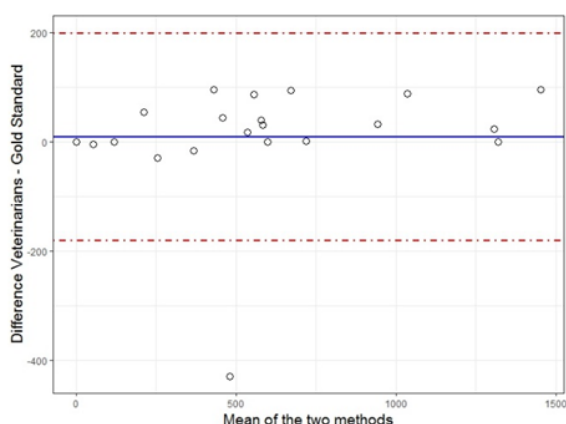


Figure 5-9. Bland-Altman plot comparing veterinary sales data with gold standard data for teat sealants in total number of tubes.⁹

Veterinary sales data may give values between 181.78 tubes of teat sealant below the gold standard method to 198.78 tubes above it (Table 5:3). However, this result needs to be interpreted with caution because the differences between both methods were not normally distributed even after log transformation. In such cases, the estimated limits of agreement tend to be too far apart rather than too close and should not inadvertently lead to the acceptance of poor methods of measurement. The Bland-Altman plot revealed one large outlier (Fig 5-9). Removing this outlier improved the closeness of the distribution to normality but did not solve the problem. However, this outlier had a big impact on the limits of agreement. After excluding this outlier, the mean difference became 26.04 (i.e. on average the veterinary sales data measures 26 tubes less than the gold standard) and the 95% limits of agreement were 49.50 tubes below the gold standard and 101.58 tubes above it. The ICC of teat

⁹ The y-axis represents the difference between the two named methods, and the x-axis represents the mean of the two methods. Dots represent the mean difference between the methods for each participating farm. The blue line represents the mean difference between methods across all farms and the red hashed line represents the 95% limits of agreement

sealants is presented in Table 5:4 and showed excellent reliability. However, the clinical interpretation of agreement showed poor agreement (Table 5:5).

Teat sealant use is not currently a requirement of the VARSS report, although the new RUMA Targets Task Force AMU targets include a target to increase the use of mechanical teat sealants in dairy cattle (Responsible Use of Medicines in Agriculture Alliance, 2017). It is therefore likely that teat sealant use will be measured in a similar way to AMU in the UK dairy herd, and data on the best way to measure use is valuable. As shown in this study, veterinary sales data is again the best proxy for actual use when measuring teat sealants, although data in this study were very skewed by one farm. While it could be argued that removing this one farm with outlying data does not give a true picture, considering both the complete dataset and the dataset without this farm provides a more complete picture than either result alone. It is possible that this farm already had 12 months of teat sealant in stock at the beginning of the study, thus skewing the data by underestimating use for the period. Skewing of PVM use data in this way may be the norm on some farms and therefore should be taken into account and not omitted from the analysis, but only through a study with a larger dataset across a greater number of farms can this be known.

5.5.2 Differences in agreement by medicine type

The type of medicine being measured had an effect on the reliability and agreement for both measures where ICC were calculated: veterinary sales data and medicine waste bins. As can be seen in Table 5:4, for veterinary sales data, injectable antimicrobials, intramammary antimicrobials all injectables, and teat sealants showed excellent reliability with ICC and 95% confidence intervals >0.9. However, when measuring vaccines, veterinary sales data showed moderate to excellent reliability with ICC 0.878 and 95% confidence intervals 0.749 to 0.943; other forms of antimicrobial showed only poor to good reliability with ICC of 0.727 and 95% confidence intervals ranging from 0.481 to 0.867. When using the clinical interpretation seen in Table 5:5, the differences were more stark. Injectable antimicrobials

showed good clinical agreement, intramammary antimicrobials showed moderate agreement, teat sealants showed moderate to good agreement and the medicine types 'other' antimicrobials, all injectables and vaccines showed poor agreement.

For medicine waste bins, the differences in statistical reliability between different medicine types are also shown. Injectable antimicrobials, all injectables and vaccines all showed good to excellent reliability with ICCs ≥ 0.9 and 95% confidence intervals between 0.790 and 0.966. Intramammary antimicrobials showed moderate to good agreement with an ICC of 0.789 and 95% confidence intervals of 0.586 to 0.899. 'Other' antimicrobials and teat sealants were shown to be systematically different and therefore showed no statistical reliability. For clinical agreement, as shown in Table 5:5, only injectable antimicrobials showed moderate to good agreement, while intramammary antimicrobials, all injectables and vaccines showed poor agreement, 'other' antimicrobials and teat sealants showed systematic differences and therefore no agreement.

The differences seen between the measurement of different types of PVM are an interesting result. These differences may lie in a number of physical and social factors. Some of these differences may be explained by their different physical characteristics of the medicines (i.e. throwing away an intramammary tube or 100ml bottle of injectable product is easy and likely to be remembered, whereas throwing away a torn sachet of powder may be forgotten), the relative importance a farmer places on that medicine (antimicrobials may be seen as of greater importance than anti-inflammatories and therefore recorded and disposed of more accurately), geographical location of use (intramammary antimicrobials are likely to be administered in the milking parlour and therefore near a bin and a whiteboard for record keeping whereas an eye ointment might be administered in the field, without ready access to a medicine bin or recording book). These differences between recording methods for different types of medicine require further work to investigate the factors at play.

5.5.3 Method of measurement

When compared against the gold standard, the three different methods of measurement showed varying levels of agreement. Each method of measurement was subject to a repeated measured on-way ANOVA initially in order to determine whether any methods showed a systematic difference to the gold standard. For all types of medicine measured, farm medicine records showed a systematic difference to the gold standard. As such, farm medicine record data could not be included in any further analysis beyond this initial stage, and for this reason results for this method is not reported alongside the other methods of measurement beyond the results of the ANOVA.

The reliability between methods was measured using the ICC which reflects the degree of correlation and agreement between measurements. This method has been used previously when comparing medicine waste bin use with farmer recall in a small study of Peruvian farms (Redding et al., 2014) and is advocated in Watson and Petrie's 2010 review of the correct methodology for method agreement analysis (Watson and Petrie, 2010). However, as previously described in the Data Analysis section, the ICC shows statistical reliability but does not relate agreement to the clinical context. As such, it is important to pre-define acceptable clinical limits of agreement (Watson and Petrie, 2010), as was done in this study.

5.5.3.1 *Veterinary Sales Data*

Veterinary sales data showed the best levels of agreement with the gold standard when measuring all six different medicine types. Agreement was best - excellent reliability ($ICC > 0.9$) - when measuring all injectable PVM ($ICC = 0.999$), injectable antimicrobials ($ICC = 0.998$), intramammary antimicrobials ($ICC = 0.995$) and teat sealants ($ICC = 0.976$).

Clinically, veterinary sales data also showed the best levels of agreement, with good agreement for injectable antimicrobials, moderate to good agreement for teat sealants and moderate agreement for intramammary antimicrobials. It showed clinically poor agreement with vaccines, all injectables

considered together and other antimicrobials, although still proved to be superior to the agreement for the other two methods for these medicine types.

While veterinary sales data shows the best agreement with the gold standard, this does not mean it exactly represented the gold standard. While the fact that the limits of agreement cross zero in almost all instances means that veterinary sales data has the potential to exactly reflect the gold standard, this also means that in some other cases veterinary sales data can over- or underestimate actual use as measured by the gold standard. In general, the Bland-Altman plots showed an overestimation of use when measured by veterinary sales data, although the degree of overestimation varied between medicine type being measured.

5.5.3.2 *Medicine waste bins*

Medicine waste bins have been used in academic research to measure antimicrobial use on dairy farms (Redding et al., 2014, Nobrega et al., 2017, Saini et al., 2012). However, as presented in Chapter 2, there has not been any validation of the levels of agreement between the data provided by medicine waste bins and the actual use of medicines on farms.

The results of this study indicate that medicine waste bins show good to excellent reliability when measuring injectable antimicrobials, all injectables and vaccines, and moderate reliability when measuring intramammary antimicrobials; however, there was a statistically significant bias when measuring other antimicrobials and vaccines and therefore agreement could not be measured. Clinically, medicine waste bins showed moderate to good agreement for injectable antimicrobials and poor agreement for intramammary antimicrobials, all injectables and vaccines.

This study is the first to show that while medicine waste bins do show moderate to good agreement with actual on-farm use for injectable antimicrobials, they are less accurate for the other types of medicines. This study has also demonstrated that the data provided by medicine waste bins was inferior to that provided by veterinary sales data when compared with the gold standard. Medicine

waste bin audits were also more time-consuming, labour-intensive, and required greater farmer acceptance and compliance. Their use may be justified and potentially preferable in cases where obtaining veterinary sales data is difficult due to its non-existence or data protection issues, but, in most instances using veterinary sales data in the UK context would be the superior method of estimating use.

5.5.3.3 *On-farm medicine records*

The results of this study show that on-farm records are not currently a good proxy for on-farm PVM use because their measures have been shown to be statistically different to the gold standard for all medicine types studied. This may initially appear counter-intuitive, as farm assurance requirements for on-farm medicine records should mean they provide detailed and accurate data that is temporally correct and therefore superior to other sources of use data. However, as shown by previous literature and known anecdotally by many veterinary surgeons and farmers, on-farm medicine records are often seen as an unnecessary bureaucratic burden and of little value to farmers (Escobar, 2016). The variability and inaccuracy of the on-farm medicine records in this study may be attributed to the lack of value that farmers place on medicine records, as shown by Escobar and others (Escobar, 2015). Where farmers do not believe in the intrinsic value of record-keeping, they are unlikely to prioritise maintaining those records.

Given the results of this study, it is suggested that work needs to be done to improve the quality of farm medicine records before such data can be relied upon to measure antimicrobial or PVM use; for instance, providing farmers with easy-to-use data entry platforms that are integrated with veterinary sales and cattle movement records. There are published studies which have relied solely on farm-based records for quantifying antimicrobial use in countries other than the UK (Stevens et al., 2016, Gonzalez Pereyra et al., 2015), and further research is necessary to ensure the validity of these data.

Farmers are now required to submit antibiotic usage data annually for farm assurance purposes (Red Tractor Assurance, 2017) and AHDB are currently piloting eMB Cattle (personal communication) which will include the ability to submit antibiotic usage data online. If these data are to be used in the future for AMU surveillance, it is important to acknowledge and attempt to mitigate the current poor quality of farmer-recorded data. However, it is possible that simply through providing a streamlined, uniform data submission process, data quality may improve. It is also possible that data quality would deteriorate through false recording, particularly if the record kept were to be used for benchmarking and target-driven bonuses or penalties. It is therefore essential that the quality of the data being entered into any potentially mandatory new recording system be fully measured and validated.

5.5.4 Limitations

The relatively small number of farms involved in this study mean that there is a risk of bias from outliers and the potential that these farms do not represent the wider sample population. Despite this, the number of farms was in excess of that required by the sample size calculation in order to show an expected excellent reliability. While it has been suggested that, as a rule of thumb, 30 heterogeneous samples should be taken in order to calculate ICC (Koo and Li, 2016), it has elsewhere been suggested that sample size can be calculated based on the expected ICC and the lower acceptable limit of the 95% confidence interval (Walter et al., 1998) which was used in this study and the minimum sample size surpassed. The limitations of non-normal data, the removal of outliers and data transformation have been discussed individually as they occur in this section.

With the different recording methods, there were several areas for potential discrepancies. Bin use is farmer-dependent and relies on the farmer remembering to use the bins and using them correctly. This means that there is a chance that some conscientious farmers were more likely to use the bins regularly and accurately. Conversely, a farmer forgetting to (or choosing not to) use the bins would have affected the results. It is difficult to say whether farmers who used the bins less well also

maintained less accurate on-farm medicine records due to the small sample size of this study, although this is a possibility and could have introduced bias into the study.

Another limitation of this study, it could be argued, was the number of different formats in which the on-farm medicine records were presented. Farmers were asked to provide “their normal medicine records, in the way they would normally record them”. This ranged from detailed computerised records linked to individual cow identification and tag numbers through to pencil marks written on the side of a bottle. While these different formats mean data were recorded with varying degrees of detail, this was a true reflection of the real “on-farm” data present and, as such, it was part of the study design to accept on-farm records in all forms. The alternative would have been to provide a standardised medicine record format; however, this would have the potential to change the recording behaviour and would not have reflected true practice.

Similarly, veterinary practice data was made available in various formats. These were all computerised records, with some practices sending through Excel (Microsoft Office 365) spreadsheets and others sending through scanned print-outs of invoice data. Although these differing formats made data assimilation more time-consuming and painstaking, it was not believed that this had an effect on the quality of the data collected.

Developing a “gold standard” for PVM use was necessary for this study in order to have a comparator for the three methods of recording, none of which had previously been validated. The definition of gold standard used for this study was: “a benchmark that is the best available under reasonable conditions. Indeed, is not the perfect test, but merely the best available one that has a standard with known results. This is especially important when faced with the impossibility of direct measurements.” (Cardoso et al., 2014). The actual “ground truth” use of PVM on farms is almost impossible to directly measure over a 12-month period without direct observation. Through discussion with a data scientist and epidemiologists, the gold standard used in this study was agreed to be the best available measure

under reasonable circumstances. This gold standard is itself open to bias, given that it is based on veterinary sales data combined with on-farm inventories. If a farm were to source PVM elsewhere, or PVM were somehow omitted from the initial or final inventory, this would affect the gold standard use value. Sourcing PVM elsewhere appeared not to be a major factor on participating farms; farmers were asked whether they used more than one veterinary practice or procured PVM from other sources - PVM on farms were generally labelled by the prescribing practice and there was only one instance of a foreign PVM being found on a participating farm. PVM inventories were carried out diligently, and as set out in Chapter 4 Section 3, therefore the risk of omitting PVM was kept to a minimum.

Several assumptions were made when collecting and analysing the data, as laid out in Chapter 5 Section 3. Where labels had perished on PVM items found in waste bins and the type of medicine was unidentifiable, these PVM were disregarded. Although the number of medicines this applied to was small ($n=14$), this would still lead to an underestimation of PVM use based on medicine waste bin data. Where PVM items in the inventories or in the medicine waste bin were opened and contained some remaining medicine, the quantity remaining was estimated to the nearest 10% by eye. Ideally, it would have been possible to obtain reference weights for each PVM type and use a portable weigh scale to more accurately estimate the quantity of PVM remaining. Estimation by eye was used due to the speed and simplicity of these estimations, although over- and underestimation of actual medicine remaining was possible. Final inventory visits and bin collections were carried out on the 12-month anniversary of the study \pm 3 days. This led to a potential 6-day difference in the length of time some farms were studied, although it was assumed that this would be unlikely to significantly affect the farm's medicine recording given that for each farm the veterinary sales data and on-farm medicine records were measured for the same time period as the bins were present.

5.6 *Conclusions*

The use of veterinary sales data as a proxy for actual on-farm use of PVM is justified based on the results of this study. While there were some limitations to the study, these were largely mitigated against and, given its exploratory and original nature, these results could be used as evidence to inform policy decisions until further research can validate the findings.

The acceptable limits of agreement between different recording methods when measuring medicines are a clinical, not statistical, decision. This explains the occasional disparity between the statistical determination of agreement as shown by the ICC, and the clinical interpretation of agreement when measuring different types of medicine. Whether a method agrees with the gold standard is important. However, whether the level of agreement represents what would be clinically acceptable when measuring veterinary use is more important.

Since the gold standard is not currently a feasible way of measuring actual use of veterinary medicines on farms, veterinary sales data provides the best available proxy for use, with the best available levels of statistical and clinical agreement. Medicine waste bins provide acceptable levels of agreement with the gold standard when considering injectable and intramammary antimicrobials. On-farm medicine records do not provide acceptable levels of agreement with gold standard measures of use for any medicine type.

5.6.1 Future work

The results of this study should be seen as “pilot data” to inform further research designed to validate veterinary sales data and on-farm medicine records as proxies for actual PVM use. Further research should include a larger study with a greater number of farms, distributed across the UK in order to assess the generalisability of the results. It would also be useful to repeat this study on different types of farms where data on medicine records and PVM use is even less available, namely beef farms, sheep

farms, mixed holdings and small-holdings. It would also be useful to conduct similar research in other countries, in order to assess the similarities or differences between recording methodologies internationally. Previous published research quantifying AMU on farms have relied on farm-based medicine records (Stevens et al., 2016, Hyde et al., 2017, Gonzalez Pereyra et al., 2015), and it is vital that more research is undertaken to assess the validity of these data internationally.

If and when a new computerised medicine book is introduced for use in UK cattle farming, it would be very useful to conduct similar research in order to evaluate the potential impact of a nationally coordinated online recording method for farmer-inputted data. The results of this study do not support the use of on-farm records in their current form due to the fact that they do not agree with the gold standard for use. There is, however, much potential for improved quality of data with an improved data collection system.

5.6.2 Policy implications

The current move towards using veterinary sales data as a proxy for on-farm medicines use appears to be justified based on the results of this study. Further work to validate these results and the ongoing implications for national recording is required. The use of medicine waste bins in academic studies appears to be justified when measuring injectable and intramammary antimicrobials. The use of medicine waste bins also represents the best alternative method of recording use when veterinary sales data are not available.

Despite the potential for more temporally accurate and granular data to be available through the use of on-farm medicine records, the results of this study indicate that these data are not currently of good enough quality to be used as a proxy for actual use on dairy farms. It is important that before any decisions are made to move towards using this form of data collection, efforts are invested in improving the quality of these records and validating the data.

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

Chapter 6 Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

6.1 *Abstract*

The use of prescription veterinary medicines (PVM) on UK dairy farms is complex. Understanding the way in which PVM are used through quantitative means alone is limited. By using qualitative research methodologies, it is possible to begin exploring the context and meaning behind treatment decisions, in addition to the beliefs and motivations driving those treatment practices.

In this study, three North Somerset dairy farms were enrolled to a 12-month participant observation. Additionally, 20 semi-structured in-depth interviews were conducted with dairy farmers from South West England and South Wales. Qualitative data were collected in the form of interview transcripts and ethnographic fieldnotes. These data were analysed qualitatively, using iterative-inductive thematic analysis.

Four key themes were identified that had a direct or indirect relevance to medicine use and treatment decisions: knowledge, trust, autonomy of treatment practices and a duty of care. These themes contain several sub-themes which relate to specific values and practices observed or discussed on the participating farms. The study highlights important areas for focus when aiming to influence or improve medicine use on dairy farms, both for policy makers and the veterinary profession.

6.2 *Introduction*

Veterinary medicine use on UK dairy farms is complex and can only be partly understood through quantitative means. Improving our measurement of the medicines prescribed by veterinary surgeons, while crucial, is only one piece of the jigsaw. In order to create as complete a picture as possible, the subject must be explored through multiple methodological lenses (Buller et al., 2015).

For example, consider a single antimicrobial: oxytetracycline. Knowing that a farmer purchases 15 bottles of oxytetracycline injectable solution in a year, when previously he or she had purchased 2-3 bottles per year is important. However, simply measuring the quantity purchased does not explain to us why this farm's need for this antimicrobial has increased so dramatically. While the veterinary surgeon may, and indeed should, have some insight into the reasons for such an increase, these reasons are usually only superficially measurable in a quantitative way. Only by speaking to the farmer and being present to observe the daily use of this antimicrobial can the picture be informed with the richness and detail required to understand the reasons and drivers of actual antibiotic use. Many veterinary surgeons are perhaps lay-ethnographers in this respect; they gain their in-depth understanding of a farm through multiple interactions with the farmer. By questioning, participating in and observing the operation of the farm, the veterinary surgeon builds a picture of the context and the culture of the farm and thus begins to understand the complexity of medicine use practice. However, because most veterinary treatments on dairy farms are administered in the absence of the prescribing veterinary surgeon, the current study has focussed instead on the treatment decisions and medicine use practices of farmers in order to build a picture of the on-farm cultures and practices when the farm veterinary surgeon was not present.

This thesis argues that these on-farm cultural practices and the contexts within which treatment decisions are made by individual farmers are of equal significance to quantitative epidemiological data

relied upon so heavily by veterinary research and government policy, as discussed in Chapter 2 (2.4.1). Management practices on farms depend on the unique circumstances experienced by different farmers, along with their goals and values (Ritter et al., 2017). Indeed, there may be no obvious logical reason for management decisions made by farmers when viewed by the outside observer (Kristensen and Jakobsen, 2011). As such, in order to develop effective policy interventions and knowledge exchange programmes, and promote productive communication, it is necessary to improve our understanding of how treatment decisions are made, how practices of medicine use are engaged across the unique circumstances on individual farms, and to explore farmers' goals and values.

The Health Belief Model (Janz and Becker, 1984) and Theory of Planned Behaviour (Ajzen, 1991) - discussed previously in Chapter 2 - are certainly over-represented in qualitative enquiry of farmer behaviour (Buller et al., 2015, Ritter et al., 2017). This thesis posits, as others have, that the limitations of those constructs can lead to an incomplete understanding of the situational contexts and cultural practices that determine medicine use (Buller et al., 2015).

The government regulations, the economic pressures, and the farm assurance and disease surveillance programmes to which a farm is subject - which can be described as the wider farming context - are constantly changing. In addition, the narrower context of staffing, weather, animal health and the personal lives of farmers, along with numerous other factors, are in continuous flux. Since the farmer's context can affect their decision making (Ritter et al., 2017), it is therefore vitally important that research into decision making on farms is capable of including and reflecting upon the impacts of these contextual variations.

By using an ethnographic approach, this research observed and analysed farmer behaviour as it occurred. Ethnography has been described as being able to examine "social life as it unfolds, including

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

looking at how people feel, in the context of their communities” and provides an understanding of “social life as the outcome of the interaction of structure and agency through the practice of everyday life” (O'Reilly, 2012, top of page 1). Ethnography has the advantage of the researcher being present and asking questions for a prolonged period of time, believing that “relevant and interesting information is more likely to surface in informal context than in formal interview settings” (Pool and Geissler, 2005, top of page 16). There is a difference between what people say, what they think, and what they do, and it has been argued that ethnographic research is best placed to understand these differences (O'Reilly, 2012, Lambert and McKeivitt, 2002).

The aim of the study presented in this chapter was to improve understanding of the practice of veterinary medicine use, by exploring the values, motivations, culture and practices of UK dairy farmers when using PVM. Ethnographic in nature, the study involved 20 UK dairy farmers taking part in semi-structured qualitative interviews (n=20) along with a 12-month participant observation study conducted across three UK dairy farms (n=3).

This chapter will describe the research methods used, outline the four key themes which have emerged from the data and discuss their relevance to the current literature, their implications for policy and the areas where further research may be required.

6.3 *Materials and Methods*

As discussed in detail in Chapter 3, ethnography as a methodology can take many forms through the use of different research methods. The most common and fundamental research method used in ethnographic research is that of ‘participant observation’, while semi-structured in-depth interviews, focus groups and other qualitative research methods can all contribute to the overall methodological approach.

In the study described in this chapter, participant observation and semi-structured in-depth interviews were performed concurrently rather than sequentially. That is, while they occurred at different times and on different farms, participant observation visits took place on three farms over the course of 12 months and were interspersed with visits to collect semi-structured in-depth interviews from other farms, in order that through reflexivity the participant observation could inform the interviews and *vice versa*. Recruitment of farms, ethical approval and participant consent for the research are described in detail in Chapter 3 and, where necessary, are expanded upon below.

The positionality of the researcher is of great importance when conducting ethnographic research. In this instance, the researcher and author (GR) was a veterinary surgeon with a background in farm animal and equine practice, although she was no longer in clinical practice. However, the researcher's veterinary qualifications were not volunteered to participants; instead she introduced herself as a research student from the University of Bristol. Where participants enquired further, her veterinary qualifications were not concealed.

6.3.1 Semi-structured in-depth interviews

Participants for this study were recruited as described in Chapter 3. Briefly, veterinary practices in the study area (South West England and South Wales) were approached and asked to nominate dairy farmers to take part in a 12-month mixed-methods study investigating PVM use. Twenty-seven farmers were recruited to the wider study using maximum-variation purposive sampling, along with two farmers who were recruited to the pilot study (n=29). All 29 farmers were invited to participate in a semi-structured in-depth interview exploring their beliefs, values and motivations about veterinary medicine use. Of these 29 farmers recruited to the wider study, 27 agreed to take part in the interviews. For those who declined to be interviewed (n=2) the reasons given were a "lack of time"

(n=1) and being “too shy to be recorded” (n=1). From the pool of remaining participants, 20 farmers were interviewed once by the author (GR) over the course of 24 months.

Interviews began with the two participants involved in the pilot study. After this, interviews took place in clusters of three to five interviews at a time according to the schedules of both the participants and the researcher (GR). Participants were not interviewed in any predetermined order other than occasionally being arranged according to geographical location where the researcher was likely to be at the opportune time. As described in Chapter 3, interviews were conducted on the participants’ respective farms. Interviews were usually conducted at the kitchen table or farm office with a cup of tea: however five interviews were collected out on the farm, either in the dairy, on the farmyard or in the cow shed. Participants were reminded at the commencement of the interview that it was to be recorded and their permission for this was requested at each and every interview. The interview was presented as a relaxed and far-ranging chat about their opinions and thoughts on various aspects of medicine use. It was stressed at this point that there were no right or wrong answers and that participants should feel free to ask questions for clarification at any point, as well as suggest other areas for discussion. The researcher (GR) introduced herself as a researcher from the University of Bristol and did not disclose unless asked that she was a veterinary professional.

Interviews broadly followed the topic guide in Appendix 9; after the initial 3-4 interviews, however, the guide was only referred to towards the end of the interview to ensure all areas of interest to the researcher had been covered. Participants were found to be very forthcoming in the main, and often the topic guide was not necessary as the interview would naturally cover the areas of interest following a few introductory questions. Interview participants were in general very open to discussing the topics covered and seemed to enjoy the process. Indeed, several remarked on how pleasurable they had found being interviewed.

Following each interview, fieldnotes taken at the time were expanded upon to include reflective descriptions of the interview location, any additional persons present or interruptions to the interview, the researcher's overall perception of the openness, tone and attitude of the participant during the interview and any relevant themes or ideas from the interview that warranted further exploration.

All interviews were sent for "intelligent verbatim" transcription by the University's recommended transcription services (Bristol Transcription Services Ltd.). This form of transcription edits out repetitions and fillers such as 'ummm' or 'aaahh' while transcribing all of the interview content. Once received as Word documents (Microsoft Office 365), the researcher (GR) read through the transcripts while simultaneously listening to the audio recordings in order to detect and correct any inaccuracies or misunderstandings. This was especially important and took a considerable length of time given the technical nature of the conversations about medicines and disease, and due to the pronounced and varied regional accents presented. Transcripts were cleaned and anonymised at this stage (i.e. where names or identifiers were used during the interview, these were replaced with generic descriptors, e.g. the veterinary surgeon's name was replaced as [main vet]).

As discussed in Chapter 3, the qualitative analysis within this thesis was iterative-inductive, drawing on Braun & Clarke's Thematic Analysis (Braun and Clarke, 2006) and Glaser & Strauss' Grounded Theory (Glaser and Strauss, 1999). As such, no formal framework or initial hypothesis was set at the outset, although certain questions and areas of interest were outlined and a level of *a priori* knowledge and set of assumptions were present. The resulting themes are therefore largely grounded in, and have emerged from, the data itself. This approach, commonly used in the qualitative social sciences, has the benefit of allowing for exploration of previously unknown areas without the constraints of an *a priori* hypothesis. While grounded theory advocates a complete lack of prior knowledge or reading

around a subject and has a pre-determined model for how data collection and analysis should occur, in reality this is very difficult (Timonen et al., 2018). Additionally, grounded theory is a 'theory-generating' research methodology whereas this study does not seek to generate theory specifically but rather to describe the values and cultures present amongst dairy farmers as a basis for further research. Here, a more pragmatic approach was taken and, while the results are very much emergent from, and grounded in, the data, the analysis itself broadly followed the description of thematic analysis put forward by Braun & Clarke (Braun and Clarke, 2006) while aligning with the epistemology of ethnographic research as laid out in Chapter 3. This provides a more flexible approach to analysing qualitative data and seeks to identify and describe patterns and themes across an entire dataset.

Once the first ten interviews had been collected, transcribed and anonymised, transcripts were imported into a computerised qualitative data analysis software (QSR Software, NVivo 10) for data analysis to begin. Interviews were individually assessed, and the content was coded whereupon sections of text which referred to a certain topic or thought were tagged with a code representing that topic or thought. Sections could be tagged multiple times where it was felt that the key content covered more than one topic of interest. These codes were inductive, with a coding framework being developed from the initial five interviews and then refined over the course of analysis of the remaining data. Interviews continued, and data collection and analysis occurred concomitantly and iteratively with the emerging themes from the initial interviews being further explored and examined as interviewing progressed and as the researcher's insight evolved.

Interviews were analysed in groups of two to three from this point, as and when they were conducted. Once 20 interviews had been collected and analysed, it was determined that "data saturation" had been achieved and interviews ceased. Data saturation is defined as the point in qualitative research where the collection of further data contributes no further trends or themes than those already

apparent from previous data analysis (Kuper et al., 2008). In reality, data saturation is more of a conceptual notion than an absolute reality. With every interview something novel will emerge, and it is likely that there is never a point where nothing new can be learned. It is however possible to reach a point where the key themes are largely unchanged with each progressive interview, at which time data saturation can be said to be achieved.

All interviews were coded by the researcher who had conducted them (GR). Initially, open coding was conducted of the transcripts. During this process, memos were kept of interesting themes that appeared to emerge and areas to explore further. Once the initial open coding of interviews had taken place, axial coding was performed to identify relationships between codes (Corbin and Strauss, 2015). Codes were placed into sub-themes where the researcher felt they were on a related topic. From further analysis of these sub-themes, five main themes emerged which are discussed in the Results section of this chapter.

To ensure rigour, 10% (n=2) of interview transcripts were coded independently by a second postgraduate research student (LM) familiar with the process of thematic analysis. Both researchers then compared and contrasted the coding labels that had been developed to establish whether they captured the data in a comparable way. Although the specific names of codes differed between researchers (as is inevitable when coding independently), it was agreed that codes were broadly comparable and captured the same essence of the meanings of the data. Additionally, once axial coding and an initial template for emergent themes was reached, the researcher (GR) used member checking (Kuper et al., 2008), discussing these findings with the key informants involved in the participant observation to assess whether the results reflected their experiences. Participants agreed that the themes did accurately reflect their own experiences of medicine use and treatment decisions.

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

A total of 20 interviews were collected, with a mean length of 49 minutes and 59 seconds (Range 26:20 – 77:32). A summary of the participant characteristics can be seen in Table 6.1. Briefly the participants farmed in 7 different counties in England and Wales. The majority farmed Holstein-type dairy cows. The median age bracket of participants was 41-50 years of age; 17 participants were male and three were female. The participants farmed a median of 230 (Range 80 - 490) adult dairy cows and produced a median of 1,900,000 (Range 550,000 – 3,600,000) litres of milk annually.

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

Table 6:1 Summary of participant characteristics for semi-structured in-depth interviews (n = 20)

Farmer ID	Age bracket	Sex (M/F)	County	Number of adult dairy cows	Total annual milk production (litres)	Breed	Medicine record quality ¹⁰
1	18-30	M	Somerset	230	2,000,000	Holstein	N/A
2	18-30	M	Somerset	230	2,000,000	Holstein	N/A
3	51-60	M	Somerset	180	2,100,000	Holstein	Good
4	18-30	M	Swansea	100	650,000	Holstein	Poor
5	51-60	M	Dorset	80	550,000	Mixed	Good
6	41-50	M	Wiltshire	320	1,900,000	Holstein	Good
7	41-50	M	Somerset	220	1,900,000	Holstein	Poor
8	>60	M	Somerset	180	630,000	Jersey	Good
9	31-40	M	Carmarthenshire	80	650,000	Holstein	Variable
10	41-50	M	Wiltshire	470	3,600,000	Holstein	Good
11	41-50	M	Dorset	490	3,500,000	Holstein	Good
12	51-60	M	Somerset	150	1,500,000	Holstein	Poor
13	41-50	F	Carmarthenshire	110	500,000	Jersey	Variable
14	31-40	M	Carmarthenshire	280	1,500,000	Friesian	Poor
15	51-60	M	Somerset	340	3,000,000	Holstein	Poor
16	18-30	F	Somerset	360	2,100,000	Holstein	Poor
17	51-60	M	Hampshire	180	1,300,000	Ayrshire	Good
18	41-50	F	Somerset	280	1,700,000	Guernsey	Good
19	51-60	M	Pembrokeshire	220	1,800,000	Holstein	Poor
20	>60	M	Somerset	80	900,000	Friesian	Poor

¹⁰ Medicine records were rated Good/Variable/Poor by the researcher depending on availability of complete records throughout the study and presence of records for all PVM. Where N/A, this farm was not a part of the wider medicine audit and medicine record quality could not be ascertained.

6.3.2 Participant observation

As described in Chapter 3, participant observation is “the process enabling researchers to learn about the activities of the people under study in the natural setting through observing and participating in those activities” (Kawulich, 2005, Section 2: Definitions). Three farms from the 27 initially recruited to the project were selected for the more intensive year-long participant observation. These farms were purposively selected based on location (within 30 minutes of Bristol Veterinary School), size and management type. It was also decided that all three farms would ideally be under the care of one veterinary practice in order to minimise the differences in veterinary advice and veterinary medicines available to the farmers. To reflect as broad a range of dairy farming practices as possible, it was decided *a priori* that farms would be recruited for participant observation through maximum variation sampling to include one relatively small family farm, one average-sized farm and one larger farm which employed a herd manager.

Once these farms had been identified, a request was made during the initial recruitment visit for consent to allow the researcher (GR) to visit the farm regularly over a 12-month period for participant observation. A key informant was identified on each of the three participating farms and was the main point of contact with the researcher to arrange field visits. All three identified farms consented to this additional involvement and specific Participant Information Sheets and Consent Forms (Appendices 2 & 3) were left at each farm for a cooling off period of 14 days before being returned to the researcher.

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

Table 6:2: Summary of farm characteristics for participant observation farms (n = 3)

Farm ID	Number of adult dairy cows	Number of calves <12 months	Total annual milk production (litres)	Number of family members involved	Number of permanent staff	Number of part-time staff
A	360	140	2,100,000	3	1	1
B	600	210	4,000,000	4	7	3
C	75	6	613,000	4	0	0

Visits were arranged by telephone call or text message between the researcher and the key informant. This communication was mostly informal, and key informants would send the researcher a message if they thought an event of interest was taking place on the farm. Similarly, the researcher would maintain regular contact by telephone between visits to discuss any important changes or news to do with the farm, to arrange subsequent visits and generally keep up-to-date. The key informant was not necessarily the person that the researcher would spend time observing during the visits, and this depended on the number of staff, the duties being carried out and the time of day the visit occurred. Across all farms the researcher spent time with every member of family or staff who played a regular role in animal health and treatment decisions.

It had been decided between the researcher (GR) and the PhD supervisory team (KR, DB, HB, HL) that initial participant observation visits would be undertaken during morning milking, as discussed in Chapter 3. Morning milking was identified by each key informant on each participating farm as being the time of day where disease was most likely to be identified and diagnosed, and where treatment decisions were most likely to be made. Morning milking occurred at 4am, 5am and 7.30am across the three participating farms. Calf management and feeding took place on all three farms after morning

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

milking had finished, and therefore the majority of participant observation visits took place for the entire morning milking period plus calf management and feeding, usually finishing around midday. On occasion, visits were targeted at afternoon milking or specific days and times where the researcher had been notified of an event of interest (e.g. a tuberculosis test, vaccination of youngstock, a busy calving period, etc.).

Visits lasted a mean of seven hours and occurred approximately once a month, although this was tailored to the particular circumstances of the farm. For example, one of the farms had a seasonal calving herd, where the farm aimed to calve around 400 of the cows and heifers in a 6-week period in the spring. During this period, the researcher increased the visit frequency to every three weeks in order to capture the predicted increase in treatment decisions during the calving and immediate post-calving periods. At other times during the year visits were less frequent, occurring once every six to eight weeks.

Upon the researcher's return to the office following a field visit, ethnographic fieldnotes were expanded upon and written up in a narrative fashion. A personal observation journal was also kept, and these narrative fieldnotes and personal logs were often referred to and re-read during the course of the 12-month study. In this way, analysis of the participant observation was iterative and cyclical in nature. Areas of interest from previous visits could be identified and highlighted for further exploration at subsequent visits, informal interviews could explore possible themes and questions emerging from the data, and theories could be tested. Fieldnotes were coded in a similar way to that described for the semi-structured in-depth interviews above, however fieldnotes were kept in a written not computerised form and codes were applied to the notes *in situ* in the dedicated notebooks.

6.3.3 Data Analysis

Although data analysis has been described separately in the above sections on the semi-structured in-depth interviews and the participant observation, in reality analysis occurred concurrently and was inextricably linked. Analysis and data collection for both methodologies occurred iteratively and inductively. Themes which emerged from the earlier interviews were explored and tested during participant observation, and themes which emerged during the participant observation were explored and tested during later semi-structured in-depth interviews. The analysis presented therefore draws upon the material generated from both methods. As distinctive themes emerged from both interviews and participant observation, these were explored further during subsequent visits and refined during the analysis. Certain themes proved insufficiently substantial for further consideration while others formed the basis of the following analysis.

6.4 *Results and Discussion*

Over the course of this research, drawing upon the interviews, the participant observation and the subsequent data analysis of both, four key themes appear to strongly account for the practices of treatment decision making and PVM use on the farms investigated. These were the farmers':

- knowledge and understanding of the treatment of disease,
- conditional trust in the actors involved in the treatment process,
- treatment practices and the frameworks within which they occur, and
- sense of duty to the care and wellbeing of their animals.

Each of these were seen to directly or indirectly affect the observed treatment decisions and practices being carried out over the year-long participant observation. Each will now be discussed in turn.

6.4.1 Knowledge

“Father's said many a time you're never too old to learn if you're not too stubborn to listen.” –

Farmer 5

Knowledge has become a value-laden term in epistemology, however in this context the knowledge that farmers speak of refers to what they see as the positivistic “truths” about the physiology and pathology of disease processes, medical pharmacology and the management of animal health. Farmers have an acute awareness of the limitations of their ‘formal’ knowledge yet rely strongly on experiential and experimental knowledge that can, on occasion, put them at odds with the more ‘evidence-based’ medical knowledge of their veterinary surgeons.

Within the overall theme of knowledge, four clear dimensions are discernible as presented in the four sub-sections below. Here the four dimensions of knowledge are teased out: experiential, experimental, uncertainty and conceptualisation.

6.4.1.1 Experiential knowledge

Experiential knowledge describes the impact of past experience on farmers’ current knowledge about farming, disease and treatment. The majority of farmers interviewed had many years of experience in dairy farming, and in agriculture more generally, and would regularly refer to their previous experiences when discussing treatment or management choices. This experiential knowledge was used in many contexts to justify treatment decisions, in particular where those decisions may be considered contentious or going against their perception of the social norm.

Experiential knowledge was most commonly articulated in the form of anecdotal evidence of previous treatment successes or failures, as has been described in other work (Hektoen, 2004). The outcomes of previous treatment decisions proved to be a key factor in the decision to treat, which medicine to

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

use, and in what quantity. This can be described as a degree of 'path dependency', where decisions follow a pathway laid down by the perceived success or failure of previous decisions. As one farmer succinctly put it:

"It's worked in the past so why shouldn't it work in the future?" - Farmer 5

Equally, where a treatment has failed to 'work' (i.e. has failed to result in recovery from disease) it is written off as ineffective and a farmer would not consider using it again under normal circumstances. Interestingly, one farmer did reflect on this practice and appeared to accept that the medicine may be effective despite the treatment failure:

"No, never found it worked but it probably does and it just could be just that I've tried it, didn't work on one animal and I've just kind of thought, this doesn't work. You kind of get used to certain tubes and how easy they are to apply sometimes as well." - Farmer 17

This quote also demonstrates that experiential knowledge is not only rationalised, it is also embodied. For example, how 'easy to apply' a medicine may be is learned from past experience and can also contribute to the perception of prior successful use, rather than simply the effectiveness of the treatment in inducing recovery from disease.

There is a well-known phenomenon of confirmation bias whereby new evidence tends to be used to confirm one's existing beliefs (Nickerson, 1998); it is known to affect the treatment decisions of human medical clinicians (Saposnik et al., 2016) as well as veterinary surgeons (McKenzie, 2014). In dairy farming, there is little published specifically on the influence of anecdotal evidence on treatment decisions, however Swinkels' (2015) work on mastitis treatment touches on the subject. Equally, in medical anthropology the distinctions between the experience-based knowledge of healthcare

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

professionals and those of non-professionals are well-documented, with both ‘formal’ and ‘informal’ knowledge playing an important role (Pool and Geissler, 2005).

More generally, farmers believed their own experiences of dairy farming to be of great value to themselves, their animals and their farms (Buller and Roe, 2016). It is important to note that experiential knowledge was not always limited to that individual’s experiences, but also the experiences of generations that had farmed before. Given the generational nature of family farms, this experiential knowledge is a commodity passed from parents to their children. In this way, while scientific understanding of disease processes evolves, and the medicines used to treat disease advance, the science may be of lesser value to a farmer than the understanding of disease gained through personal and familial experience.

Under certain circumstances farmers believed experiential knowledge to be superior to knowledge acquired from veterinary surgeons or from other “expert” sources (in this case knowledge exchange meetings organised by the national dairy levy board, AHDB):

“Yes, I think I know how to look after a cow now. I don’t think I need to go to a meeting unless – I don’t want to be blasé mind you, but I think I know that my cows all look well and I don’t need to go to a meeting. It’s all repetitive stuff that I basically know already.” – Farmer 20

In one example from the ethnographic fieldnotes, a farmer described the tensions between, on the one hand, the advice and “scientific knowledge” being given by their veterinary surgeon about the best way to manage a recent outbreak of pneumonia in their calves; on the other hand, the advice and “experiential knowledge” of their grandfather. Here, the farmer’s veterinary surgeon had advised vaccinating the calves against certain respiratory diseases in combination with investment in individual calf hutches to reduce the disease burden. The farmer’s grandfather on the other hand

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

disagreed and advocated placing heaters in the calf shed while treating all of the calves with a dose of long-acting antimicrobial because “this has always sorted the problem in the past”.

In this example, the confrontation of modern scientific understanding and experiential knowledge caused obvious tensions between the farmer, his veterinary surgeon and his family. In negotiating a resolution, a ‘compromise’ of sorts was reached whereby the farmer treated all of the calves with an antimicrobial while also beginning to research the purchase of individual calf hutches for the next season. This example illustrates the tensions between these two forms of knowledge, and the impact that they can have on medicine use.

6.4.1.2 *Experimental knowledge*

In addition to experiential knowledge, which can perhaps be described as passive knowledge acquisition, farmers use experimental knowledge when making treatment decisions (Farrington and Martin, 1988). Here, they actively test and trial different medicines, treatment and management practices in order to find which work best.

“It’s just something that we’ve tried over the years and it works, so that’s what we do. When they calve, they have one of those five-in-one tubes. It’s just got egg stuff in it and it’s just protein and egg, but we find... we’ve done our own little experiment here on calves that have had newborn tubes and calves that haven’t had newborn tubes, and the calves that have newborn tubes will be far thriftier than the calves that don’t. So it’s something that we’ve done here ourselves...” – Farmer 13

Often, this knowledge is experimental and acquired by design. Occasionally, such knowledge may be gained accidentally:

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

YG [young female staff member carrying out morning milking], on finding a cow that needs treatment fetches a Mastiplan intramammary tube from the medicine cupboard. She pulls the lid away from the tube in such a way that the infusion tip becomes bent at an approximately 45° angle from straight. She then proceeds to swiftly wipe the udder, fore-strip some milk and infuse the contents of the tube before noting the treatment on the whiteboard behind her. I ask if she bent the tip on purpose, because I hadn't seen that before. "Yeah, I always do it like that". I ask if someone showed her the technique or where she learned to do it. "I guess I just accidentally did it once and realised it made it so much easier to do." – excerpt from fieldnotes, Farm B

It has been stated that “*experimenting is part of farming as much as tilling the soil, planting seeds and caring for animals*” (Haverkort, 1991, top of page 3) and the development of context-specific farming practices worldwide has been attributed to the experimental activities of farmers (Hoffman et al., 2007). There is a wealth of literature describing the various ways in which farmers use autonomous experimentation, particularly in Asia, Africa and South America (Vogl et al., 2017). Indeed, the idea of “farmer innovators” (Critchley, 2000, Reij and Waters-Bayer, 2014) and “research-minded farmers” (Biggs, 1990) is well known, and a recent Austrian study showed 90% of farmers reported experimenting in an autonomous way (Vogl et al., 2017). Farmers have also been shown to be more willing to experiment with alternatives to antimicrobial treatment for treating mastitis than veterinary surgeons (Poizat et al., 2017). The emergence of experimental knowledge as a factor in treatment decision-making and veterinary medicine use in this study should therefore be unsurprising, however it has rarely been examined in this context.

6.4.1.3 Uncertainty

While experiential and experimental knowledge both act to improve a farmer’s understanding of disease and treatment, uncertainty remains a key feature of treatment decision-making. Uncertainty

in this context can take the form of being unsure of a diagnosis, being unsure of which medicine to use to best treat the disease or being unsure about what dose is required. Uncertainty may also manifest as risk-averse behaviour: where there is uncertainty over the presence or severity of disease, antimicrobial treatments are used 'just in case', or as one farmer put it:

"It's cheaper than a dead cow" – **Farmer 2**

Indeed, in human health it has been shown repeatedly that uncertainty over the presence of pathological bacterial infection is positively associated with prescribing antimicrobials (Horwood et al., 2016, Whaley et al., 2013). Similarly, farmers have been shown to be uncertain about how to treat mastitis effectively in the Netherlands and Germany, leading to extended courses of antimicrobial treatment (Swinkels et al., 2015).

Uncertainty can arise from scenarios where determining the correct course of action is either difficult or impossible in the circumstances (e.g. whether a calf is coughing due to viral or bacterial disease). It is therefore easy to understand the rationale of making a risk-averse decision, where treating with an antimicrobial is considered low risk for the animal and not treating is considered high risk.

Uncertainty can also present as a self-identified knowledge gap. This is where the farmer knows there is a correct answer (e.g. a certain antimicrobial is clinically proven to be most effective to treat a given disease), but s/he does not have the knowledge to make an informed decision. This study has shown that farmers believe they are ill-informed about the medicines they use:

"I think medicine, the problem is there's no knowledge. I've seen my dad in the medicine cupboard literally picking up different bottles of antibiotic and thinking "hmmm, which one today?" You can go

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

to ag [agricultural] college or uni and they don't teach you a thing about medicines." – **excerpt from fieldnotes, Farm A**

Interestingly, when questioned further, farmers believed their veterinary surgeon should be the source of this information but were dissatisfied with the current provision of knowledge about medicine use. They believed their vets were often too busy to explain the correct use of medicines in enough detail, or in some instances that they did not have sufficient knowledge in this area to advise appropriately. There was even uncertainty about how to get the information and uncertainty about whether there was additional information to be had:

"Yeah, I tend to stick to the medicines that I know. That's what I was about to say. There's probably other drugs out there that I don't know about because I've always stuck to the ones that I know – the Tylan, the... it's quite boring. The Metacam, the Cronyxin; I use a bit of steroid, there's the Tylan and there's the Marbox jabs, a bit of Norodine on the calves. There's probably other stuff out there, but I think probably farmers'll stick to what they know. There could be a cheaper drug, there could be a cheaper drug – how do we find out? How do we get that information?" – **Farmer 13**

6.4.1.4 Knowledge conceptualisation

"Some people say you should be using more mammary tubes and less injection but I don't know. I just feel like with tubes there's a load of antibiotic just going in and sitting there at the bottom of the udder not really doing much. With an injection you feel more that it's getting at things from everywhere you know? I don't know if that's right through mind." – **excerpt from fieldnotes Farm B**

It became obvious from the interviews and field research that dairy farmers created their own understanding of disease, negotiating experiential knowledge, experimental knowledge, "expert" advice and their own internal logic. A narrative was needed for each treatment or medicine, and in

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

the absence of the scientific and veterinary training required to explain the processes of disease and healing farmers would develop their own understanding of disease.

An example of such a narrative, taken from the ethnographic fieldnotes, illustrates this point:

Cows from the farm start acting strangely, become very lethargic, lose weight and have reduced milk yields and at a certain period every year. The farmer believes it coincides with a time period when the milking cows are moved to a different field, near a coastal path, and associates it with a higher salt intake. In order to counteract this, he will drench each cow with warm water after morning milking every day for the 1-2 weeks that they remain on this land, "so that I can dilute the salt". The farmer says he has asked his vet about the problem, which he calls "seawall syndrome", and the vet just shrugged and said they didn't know what it might be. - Excerpt from fieldnotes, Farm C

In this example, knowledge about disease and treatment has been constructed through a combination of learned experience (the cows become unwell when on that pasture), situational knowledge (that field is near the sea and therefore salty) and pre-existing knowledge (water dilutes salt). Most notable is the absence of any input from the veterinary surgeon despite their opinion being sought.

These narratives - while powerful and with a significant influence on the diagnosis and treatment of disease - are uncertain. Farmers were aware of the limitations of their understanding: that a farmer's understanding of disease may differ from what can be considered the scientific knowledge of disease. However, in the absence of any other way of explaining their experiences with disease and treatment, this negotiated understanding was used to inform treatment decisions on a daily basis. Indeed, it has been shown that farmers who score highly in 'knowledge' during exploratory factor analysis tend to be the lowest overall users of antimicrobials (Kramer et al., 2017). In human medicine, patient literacy and understanding of disease is known to affect treatment compliance and disease management

(Gazmararian et al., 2003) and to be influenced by patients' experience of disease and the communication style of their healthcare professional (Weiss, 2007) among other factors.

6.4.2 Trust

The second major theme to emerge from the ethnographic data was trust. Trust can be described as a sociological construct referring to people's expectations (Goold, 2002). It is also an active component of agency: it underwrites social order (Lewis and Wiegart, 1985) and to a greater or lesser extent, underwrites the critical relationships on the farm. These include the relationships between keeper and kept animal, between producer and consumer and between human endeavour and natural process. In sociological terms, trust is often seen as essentially conditional; it can be earned or lost in a continuously re-negotiated relationship. In human medicine, there is an increasing focus on the value and nature of trust (Goold, 2002). A 2017 meta-analysis found a small-to-moderate correlation between trust in healthcare professionals and treatment outcomes (Birkhauer et al., 2017).

In this study, trust was interpreted as a relationship between the farmer and the different 'actors' seen by the farmers as being involved in the treatment process. These 'actors' were not always people; indeed, farmers developed conditional and relational trust in their animals, in the medicine and in the data as described below. Through interviews and observation, five aspects of trust were identified; these will now be explored in detail.

6.4.2.1 Trust in the veterinary surgeon

"Yeah I guess it varies a bit and you know, the advice. You know, where are the vets getting their advice? That changes doesn't it. Either they're newly graduated and they're using what they learnt when they studied, which is changing all the time, or they're using their, you know they're going to other sort of training courses which is off the back of new research and their advice is changing all the time isn't it? So – You know they're all generally on the same page, but obviously they're not all

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

going to be all clones of each other. They're going to have opinions and different experiences and stuff but then that's also useful, so... Yeah you do develop a relationship with certain ones that you sort of trust or with, what's the word, you sort of value their opinion more than others maybe." –

Farmer 1

The relationship between a veterinary surgeon and a farmer is important to dairy farmers (Hall and Wapenaar, 2012) and depends to a large degree on trust (Richens et al., 2015). Increased frequency of veterinary contact has been shown to improve responsible use of antimicrobials (Higham et al., 2018). The enactment of veterinary surgeons' advice on farm is influenced by a combination of the farmer's trust in the veterinary surgeon's ability, integrity, benevolence and predictability (Bard, 2018), as confirmed by the above quote. Trust between farmers and external advisors is a critical component in building the social capital required to enact advice (Fisher, 2013). Bard and others (2017) have shown that, when communicating with farmers, veterinary surgeons tend to have a paternalistic and directive style. It was hypothesised that this style of communication was one of the reasons why the uptake of veterinary advice in animal health planning was low and there have been calls for a 'paradigm shift' in veterinary communication towards a more mutualistic and collaborative approach (Shaw et al., 2006, Vet Futures Project Board, 2015).

Farmers emphasised the value they placed on trust when discussing the veterinary surgeon-farmer relationship. Once trust has been earned, it is seen as stable and difficult to lose. However, before it is earned, the initial interactions between a farmer and a new or unfamiliar veterinary surgeon are critical and likely to set the course for the relationship in the long-term:

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

“First impressions make a massive difference for quite a long time. Male vets, especially new ones, sometimes they’re too cocky. That’s why we always sway towards the women” – excerpt from fieldnotes, Farm C

The importance of the first impression made by the veterinary surgeon appeared frequently in farmer interviews and was deemed as difficult to re-negotiate once the assessment had been made. However, there was also an acknowledgement of the veterinary surgeon’s ability to redeem themselves and ‘earn’ the trust of a farmer through an act of unexpected successful veterinary intervention:

“Farmers are pretty typical like they have their favourite vet on the farm and it’s always guilty until proven innocent. ‘That new vet’s bloody useless rah rah rah,’ but then they turn up one morning and save a cow and all of a sudden they’re the best thing ever.” – Farmer 1

The veterinary surgeon was viewed as an important source of information on disease control, due to their knowledge of on-farm animal health and the local disease epidemiology (Gunn et al., 2008). However, there were reported discrepancies between the veterinary surgeon’s perceived role and the preferences reported by farmers (Hall and Wapenaar, 2012). This discrepancy may lead to a breakdown in communication, advice uptake and, ultimately, trust. Where advice is sought or given on medicine use or treatment decisions, integrity is particularly highly valued:

“I also think the drug companies have got quite a big lean on quite how they push certain ways of doing things. Because they tend to lead the vets into saying, “Right, this is the way to do it.” Because that’s how they get told it. I am not saying the vets are misleading or doing anything deliberately, I just think the industry has a nasty habit of being led...” – Farmer 6

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

In the above example, the farmer was explaining why he would deliberately choose to ignore the advice of his veterinary surgeon about which medicines to use, and instead do his own research. This suggests that a lack of trust in the vet and their advice, or indeed the manner in which this advice is given as shown by Bard and others (2017) can directly impact treatment decisions. This may, in turn - and depending on where alternative advice or knowledge is sourced - lead to inappropriate or irresponsible medicine use.

6.4.2.2 *Trust in the staff*

While trust in the veterinary surgeon influenced the uptake of advice, this was often only the first step in the decision-making process. In order to enact this advice, there must also be trust in the person delivering the action. In this case, this action is the diagnosis and treatment of disease. The majority of farms employ some staff, either unofficially (where a farm is run by various family members who all have a stake in the business) or officially (where external employees are hired to carry out work). The roles of staff members can vary significantly between farms, but in most cases staff will be interacting directly with the cattle and will have some responsibility for animal health. Animal care is seen as physically demanding, containing elements of care work and emotional work (Brandth, 2006).

Dairy farmers in the US have been shown to underestimate the satisfaction of their staff, and also the willingness of staff to learn animal management and dairying skills (Durst et al., 2018). On the other hand, dairy farmers place great value in capable staff, which impacts on their decisions to treat diseased animals (Horseman et al., 2014):

“My attitude is a good herdsman deserves double, a bad one deserves to pay you really” – Farmer 3

“To build a team of three people has taken me – a team as good as this has probably taken me six or seven years. To find three people that will work together, fit together” – Farmer 6

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

The four aspects of trust, and the concept of a “shared understanding” described by Bard (2018) when discussing the veterinary surgeon-farmer relationship can also be seen to fit the trust relationship between farmers and their staff. This trust relationship is reliant on the farmer’s perception of the staff members’ ability, integrity, benevolence and predictability (Bard, 2018). Where one of these four areas are seen to be lacking, overall trust is lost.

A lack of trust in staff was seen in this study to lead to closer control over animal health decisions and a lack of delegation of the work of disease monitoring, diagnosis and treatment. In one case, a farmer describes not being able to leave the farm to join a family holiday due to a lack of trusted staff:

“And know that I’m not gonna come back to anything dead – well, not dead through incompetence – but I’ve been away... it does happen when I go away, so I don’t go away any more. I didn’t go away on our family hol... My husband and the kids went on our family holiday this year. I stayed home. Yeah, I just can’t do it. It’s not in my nature. If I’m coming home and finding dead things because they haven’t been looked after properly, it’s not...” – Farmer 1

Trust has been identified as an important component of the management-staff relationship in other healthcare settings (Mullarkey et al., 2011). Trust influences staff morale, the delegation of tasks and improves the uptake of advice and delivery of care (Firth-Cozens, 2004). This trust is reciprocal in nature, where increased trust by a manager results in enhanced reciprocal trust by their subordinates (Seppälä et al., 2011), although it has been shown that bosses trust subordinates more than the subordinates trust their bosses (Butler, 1986). This reciprocal trust was observed in this study to be recognised by farmers in a management position:

“To be honest there’s a cow that [herdsman] just treated, she only had one clot and I don’t think she really needed a treatment, but you can’t really criticise them for treating you know. There’s a few

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

here being treated that don't really need it I think but what can I say? If I criticise their decision then next time there's a really sick cow and it doesn't get treated because they're afraid I'll have a go then I'm not really doing my job properly, so it's "Well done. Good spot Thank you"" – **excerpt from**

fieldnotes, Farm B

6.4.2.3 Trust in the medicine

The perception of a medicine's "power" has been described by Nichter's work (1980) studying perceptions of medicines in southern India. This power (relating to its perceived potency and ability to heal) influences the decision to treat, choice of medicine and the perception of a treatment's success or failure (Relun et al., 2013). Indeed, as Pool and Geissler (2005, top of page 88) put it "Western pharmaceuticals are not only chemical substances but also social and cultural objects with diverse and often contradictory meanings and uses".

Trust in a medicine can depend on the branding and cost of purchase, with known brands increasing trust and cost being directly correlated with quality (Aivalli et al., 2018, Dunne and Dunne, 2015). Even the colour of a medicine has been shown to influence perceptions of its potency (de Craen et al., 1996). When treating mastitis, antimicrobials are regarded by dairy farmers as the treatment with the best possibility of a positive prognosis (Vaarst et al., 2003).

Treatment outcomes (or perceptions of treatment outcomes) on farms can reinforce or negate initial trust in a medicine:

"I've actually gone back to Naxcel [an injectable HP-CIA] in cows because nothing else was working... won't work, we can't get it to work." – **Farmer 11**

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

Treatment outcomes can lead to changing the medicine being used, or changing the dosage until a perceived positive outcome is reached:

We used to use Cobactan but we found it wasn't working that well. We started Mastiplan, 4 tubes but that wasn't really working either so now they get 8 tubes over four days and that seems to be working. They get a Finadyne jab and three days of 33ml Duphatrim too."

– excerpt from fieldnotes, Farm B

Where trust in a medicine has been gained or lost, this will have long-term consequences on the future use of that medicine on that particular farm. These consequences may not be seen on any other farm and are specific to the perceived performance and 'power' of each medicine on each farm. In this way, it can become difficult to predict the treatment decisions and behaviours of farmers without first understanding their particular relationships with the medicines they have available to them. Trust in medicine had different components for a farmer. Firstly, a medicine's reputation amongst peers can be an important motivator when choosing a treatment. Secondly, treatment decisions were influenced by the farmer's own experiences of the medicine: whether it was easy to use and whether it led to a positive outcome for the animal. Thirdly, trust in the medicine was linked to trusted advice: here the veterinary surgeon's recommendations for treatment can be pivotal, depending on the trust relationship that exists with the farmer.

6.4.2.4 Trust in the animal

The perception of an animal's inherent susceptibility to - or ability to recover from - disease was manifest as a trust in the animal. This trust was placed in the animal's biological processes (Bergea et al., 2016), their genetic make-up and their anthropomorphised personality traits. In one instance, a cow was recumbent in the cubicle shed following a difficult calving the previous day:

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

A cow has been down in the cubicles overnight. She'd been treated with Naxcel and Ketofen and is brought into the large straw pen using a JCB bucket. They work to get a hip hoist around her pelvis and lift her onto her feet, placing three calves onto her udder to suck while she stands. "We'll do this for a few days and see how she does. She's got daft cow disease, that's what's wrong with her" says the farm manager. - Excerpt from fieldnotes, Farm B

The development of a trusting relationship between people and animals is rooted in the process of caring for animals (Knight, 2005). Trust in the animal has been described in the context of farmer safety and farmer-animal communication (Buller and Roe, 2016). While Ingold (2000) theorised that the process of farming an animal moved the relationship between animal and human from one of trust to one of domination, it has also been argued that this explanation is oversimplified and there exists a social contract between animals and those who farm them (Oma, 2010). In the context of medicine use and treatment decisions, this trust in the animal's ability to heal can affect the energies expended in achieving that outcome. Where an animal is not trusted to recover, the decision to cull rather than treat may require a lower threshold:

"That one's knackered. Foot swelled up, treated her, she got better but now it's even worse. We just need to shoot some of them" – excerpt from fieldnotes; herdsman, Farm B

A lack of trust in an animal to recover may decrease the overall investment that a farmer is willing to make, limiting their motivation to treat. This investment refers not only to the monetary expense of the medicine, but also to the time investment required by a particular course of treatment. Animals are identified as being 'useless' or 'stubborn' where they are chronically diseased or refractory to treatment. This is despite the possibility of mis-diagnosis or inappropriate treatment and irrespective of what may be an incurable condition or guarded prognosis:

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

“This red heifer here” points at a calf recumbent flat on its side, breathing heavily “She’s a princess you know. She’s had everything right, but she’s doing everything she can to die. Typical red heifer.” –

excerpt from fieldnotes, Farm A

In human health it has been shown that low trust in the patient negatively affects the quality of healthcare provided (Gilson, 2003) and a scale has been developed to measure trust in the patient by their clinician (Thom et al., 2011). Despite this, this area of patient and clinician trust has been identified as a neglected area of research (Brennan et al., 2013). Although the farmer-cow relationship may mirror the clinician-patient relationship in many ways, it is not directly comparable due to the inability on the animal’s part to participate consciously in the trust relationship. The paediatric clinician’s relationship with their patient may reflect more accurately the imbalance of agency, however there are no reported studies of trust between clinicians and their paediatric patients.

6.4.2.5 Trust in the data

The final aspect of trust that emerged from this study was that of trust in the data available to the farmer which may be used to guide treatment decisions. This data may take the form of medicine treatment records hastily scribbled on scraps of paper, or well-organised computerised records of production data inputted by external milk recorders. Farmers recognise the variable quality of the data available to them, and their reliance on that data varies accordingly.

“They were only milk-recording every three months so I refused to do it [selective dry cow therapy] because if you have a cell count that’s two months old you just have no idea what’s going on in that udder in front of you” – excerpt from fieldnotes, Farm B

The value of maintaining good quality records was recognised but was often accepted to be sub-optimal due to time constraints, multiple people being responsible for inputting data and a relatively

low prioritisation of data collection when compared to other work. Poor data quality can lead to a mistrust in the data and present as a barrier to data-driven decision-making (Haug et al., 2013).

Indeed, farmers have been shown to have a different understanding of the purpose of record-keeping to regulators. Farmers often keep the required records for the purpose of external accountability, while maintaining separate, self-designed records for their own use (although there may also be significant heterogeneity in the quality and use of these records) (Escobar, 2015). Farmers regard paperwork as enforced and unnecessary burden and often fail to comply with the requirements placed upon them by various external regulators (Escobar, 2016).

6.4.3 Autonomy of treatment practice

The third major theme identified was that of autonomy in treatment practice. This refers to farmers' perceptions of their own autonomy with respect to treatment practices, which are focussed on the endogenous and exogenous frameworks they operate within. That is, the practical, physical and resource-specific frameworks that were in place on any farm (e.g. whether the medicine was available in the cupboard, whether staff and facilities were available in order to treat) and the legislative and regulatory frameworks that are imposed on a farm (e.g. milk withdrawal periods, farm assurance requirements). Other research has found a lack of belief in self-efficacy among farmers to be associated with lowered intent to implement disease control programs (Ellis-Iversen et al., 2010). The participants in this study expressed an acute awareness of their feelings of impotence with regard to treatment decisions and veterinary medicine use. These factors took the form of external forces, of their place within the decision hierarchy of the farm and of the physical resources available to them (Alarcon et al., 2014), each of which is discussed in turn below.

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

6.4.3.1 Regulatory frameworks

External factors create a framework - both legal and practical - within which the UK dairy farmer must work. These can take many forms: from government-mandated bovine tuberculosis (bTB) testing and control measures to farm assurance schemes, milk-buyer enforced herd health management and veterinary treatment protocols.

Farmers often related their treatment decisions directly to the limits that external forces placed on their options. An important and regularly identified constraint on farmers' decision-making regarding treatment was the issue of bTB control measures. The study areas were all in regions with a high prevalence of bovine tuberculosis; consequently farms underwent regular bTB testing of their cattle. Farmers have been shown to believe they are unable to do anything and have no control over bTB (Enticott et al., 2015). Many of the farms were under bTB restrictions where they were unable to sell young animals into the beef sector, creating issues of insufficient housing and feed. Where farms had lost a significant number of cattle to slaughter from bTB testing, they were unable to make voluntary culling decisions in order to maintain a herd size large enough to produce the volume of milk required. This inability to cull animals on a voluntary basis (i.e. where the animal is not culled due to bTB or dies) led to an increased number of chronically diseased animals on farm. Animals with long-standing issues of lameness or mastitis were being maintained within the herd, despite there often being no prospect of cure.

"I think it's getting harder and harder to be a farmer. More and more I feel like I'm just carrying out the instructions of the vet, or the Ministry [DEFRA]. Or bloody Arla [milk buyer]. Take TB for example.

I can't make culling decisions can I, if they're telling me I have to get rid of 30 odd of my best cows every year? Means I have to keep the shit ones just to stay in milk. Or antibiotics. I can't use certain

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

ones, I can't dry them off with Cephaguard, can't do this, can't do that. It gets right on my nerves." –

Farmer 19

Dairy farming is an industry particularly vulnerable to market forces, and there have been well-publicised recent periods where farmers are being paid below the cost of production for their milk. This study occurred towards the tail-end of one of those periods, and these economic constraints had a pronounced effect on treatment decisions. As one farmer put it:

"We just keep our heads down. The milk price is up but we're just paying off what we owe from when it was low. Sod's law as soon as we pay off it'll crash again. You just can't win" – **excerpt from**

fieldnotes, Farm C

By "keeping their heads down", farmers mean that they are unable to invest in their farm. This investment may be the purchase of land, new housing, new stock or just improvements to current structures. An inability to invest can have negative consequences on animal health, welfare and production (Jarvis and Valdes-Donoso, 2015). Paradoxically, this may then lead to an increased need for veterinary treatment and medicines. However, during periods of economic stress, farmers often reduce their use of veterinary services in a bid to minimise costs.

Given that 98% of UK dairy farms are members of a farm assurance scheme, it follows that farm assurance places an additional framework within which decisions about treatments are being made (Responsible Use of Medicines in Agriculture Alliance, 2017). As described in Chapter 2, the Red Tractor farm assurance scheme publishes a list of standards that must be maintained by farms, as assessed during regular farm audits. Notably in June 2018, Red Tractor announced new measures to reduce the use of HP-CIAs: veterinary surgeons could only prescribe these medicines to assured farms as a last resort where there was evidence of diagnostic or sensitivity testing that made it necessary to

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

use these medicines. While this new standard was not in force at the time of data collection for this study, it illustrates the power that farm assurance has to drive prescription veterinary medicine use at the farm level.

Farm assurance schemes have been recognised as being of limited practical value to farmers (Escobar, 2015), however given the very high uptake of such schemes in the dairy industry some value is placed on membership. While farmers recognise the necessity of being a member of a farm assurance scheme, the actual practice of enacting the standards is frequently seen as a 'tick-box exercise' that does not improve the health or welfare of the animals on the farm.

"It's a bit of a strange one, because the organic certificate, when they ask you on your annual questionnaire what drugs you've used, they only count tubes. So therefore, I will use three tubes of Tetra Delta and half a bottle of Penstrep, because it doesn't count. Which seems a bit cynical, but it works." – **Farmer 6**

On the surface, the introduction of treatment protocols on a farm reduces the autonomy of the farmer with regards to treatment decisions. Despite this, treatment protocols were overwhelmingly viewed by interviewees for this study as being a positive component of practice, with farmers finding having a protocol empowering. This can in part be explained by the feeling that a treatment protocol eliminates the uncertainty felt when diagnosing and treating disease. In this way, treatments were always able to be justified and there was no sense of needing to defend their decisions. In human medicine it has been shown that prognostic uncertainty drives antibiotic prescribing in children (Horwood et al., 2016) and the introduction of clinical decision support tools reduces inappropriate antimicrobial prescribing (Samore et al., 2005, Jenkins et al., 2013).

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

Treatment protocols were not commonplace on the participating farms. Those that did use them, however, found them very valuable in aiding decision-making and improving the relationship with their veterinary surgeon. Farms that did not use protocols expressed a desire for their veterinary surgeon to design treatment protocols which could be used on their farm. The key factor with the development of protocols appeared to be that they were designed collaboratively, and not written by the veterinary surgeon in isolation and handed to the farmer in a paternalistic fashion:

“What I’m finding with our vet is that they do respect our opinion and I think that in turn means we’re ready to listen to theirs. I mean you say about herd health plan we have been doing specific plans for specific problems, so we had a bit of a niggling issue with VLD [abnormal vulval discharge] and we now have a very nicely written up protocol” – Farmer 18

Improving responsible use of antimicrobials was seen as a benefit of introducing treatment protocols:

“It’s always been a challenge, mastitis, so we have come up with a protocol which fits our system really. We have reduced antibiotic usage massively in mastitis cows. We have used a lot of anti-inflammatories purely to help the cow through the first stages of the process of mastitis, a lot of self-cure...” – Farmer 8

Protocols were also viewed as enabling farmers to ensure that, where multiple members of staff might be responsible for treatments, treatments were standardised:

“We established a way of working and a sort of protocol, which established exactly how we should be doing things with the calves and so with new people coming along I can make sure they do exactly what we want them to do all the time in a way that we know works. We’re constantly developing that, trying to make things better all the time, and that’s an ongoing process. In fact, over the last

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

few months we've cut our antibiotic use down still further, we were fairly in control of it before." –

Farmer 13

6.4.3.2 Farming this farm

"I mean we ... because we're farmers we spend most of our day whinging about things going wrong.

That's what we do ... moaning. But in reality, it's bloody good." – **Farmer 1**

Social identity theory is based on the idea that a person's sense of who they are rests on their perceived membership of a particular social group (Turner and Reynolds, 2010). A farmer's identity is based on his or her being a farmer, and all farmers have an idea of what it means to be a "good farmer" (Burton, 2004). Farmers' social identities are dependent on context and are dynamic and complex (McGuire et al., 2013). While the idea of the good farmer has most often been explored in the context of environmental impacts and 'productivist' behaviour amongst farmers, this idea's core message was reflected in this study as was its potential to impact upon behaviour.

While the farmer's own personal identity as a farmer is clearly important to treatment decisions and medicine use behaviours, the farm itself also has an identity in the mind of the farmer. Farmers see their farms as being unique and out of the ordinary (Kaler and Green, 2013). What works on most farms does not work on others and *vice versa*. A farmer will use a certain veterinary surgeon or a certain medicine or dose because that is what works on 'this farm'. This sense of uniqueness is intimately linked with the farmer as an experimenter, developing their own knowledge of the treatments that work on their farm, with their cows. Some of this reasoning is based on scientific understanding – each farm environment will have its own microbiome, and the microbiome of each herd will be unique and different to that of the next herd. Similarly, the disease prevalence, bovine genetics and antimicrobial resistance patterns will be unique to each farm. While this is unlikely in many situations to require a different clinical approach to treatment (antimicrobial resistance is rarely

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

of clinical relevance in cattle and biosecurity and good management practices are the same across most dairy farms) the farmer needs to feel that advice and treatment decisions are being made with the uniqueness and idiosyncrasies of their farm in mind.

"The dairy industry in West Wales is different to the dairy industry in Scotland – there's regional differences in this country, let alone a different country...West Wales, with two different languages spoken, is different to being down in Kent or wherever, isn't it?" - Farmer 7

Farmers viewed their particular farm context to be important with regards to medicine use. It can be seen from the difference in medicine record quality between farms of different sizes in Table 6:1 that variation in medicine records could not be easily explained by simple demographic data, and there was no obvious correlation between size of farm, age of farmer or production levels and the quality of records kept. When looking at the interview data, farmers' views on medicine use did not appear to differ widely between farms with good medicine records and those with poor quality medicine records. This may be an example of the disconnect between intention and behaviour, and something about the context on that farm that affects the medicine record quality is missing from the data available about those farms. This is where participant observation can help, with the particular context only truly becoming visible when an observer is present on farms for a prolonged period. For example, when farmers are under-staffed and time-poor, this may lead to medicine record keeping being a low priority when compared with other more pressing tasks, despite intentions to the contrary (Escobar, 2016).

The nature of the farm's identity was seen to be heavily influenced by the farmer's potential for future investment and the situation regarding succession planning. Where farms' futures were deemed secure - perhaps where younger generations showed a committed interest in continuing to run the

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

farm - investment was likely to occur. However, where a farm's future was less certain, investment in infrastructure and new stock was less important. While this situation is understandable, it is likely to have negative consequences on animal health and the potential for increasing use of veterinary medicines in order to compensate for a lack of up-to-date infrastructure and an ageing population of cattle. The farm's future appeared to represent an attitudinal difference between farms with a secure mid-to-long term plan and those without.

"No, I'm not spending money willy-nilly. We should be re-seeding forty-odd acres, but we're just gonna manage it a bit better. I'm not spending that much money on re-seeding forty acres, especially if we decide to get out [of farming] in two or three years." – **Farmer 16**

6.4.3.3 Physical resources

As illustrated in Chapter 4, the physical resources available to a farmer will have an effect on the treatment decisions that farmer is able to make (Hektoen, 2004). Put simply, if the farmer wished to treat an animal with an antibiotic, s/he was usually limited by what was in stock on the farm. If the farmer wished to use a medicine that was not in stock, treatment was delayed while the veterinary surgeon was called out or the farmer drove to the veterinary practice to collect the medicine.

"Come to think in terms of the specific how to choose which antibiotic to use in a case of mastitis, the short answer is it depends whether it's first case, whether it's a repeat and, you know, what we've got in stock." – **Farmer 18**

Other physical resources were also important in influencing animal health and therefore treatment of disease. Where farm buildings were suboptimal, farmers might have been required to rely on the use of veterinary medicines to maintain animal health that was compromised by poor housing. Where cattle must walk a considerable distance over stony ground to reach their daily grazing, farmers may

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

need to increase the use of anti-inflammatory painkillers to treat lameness. In one case, cattle were being dried off at the end of their lactation and transported by trailer to their grazing, far away from the main farm. This situation meant that the farmer was unwilling to use selective dry cow therapy, or even to move away from the HP-CIA that they considered the most likely to reduce the risk of mastitis:

"I'd like to not use antibiotics in some cows, but because of how they get dried up here, they go in the trailer, they go to the other farm. It's just so risky, so they've recently tried to move me onto that [selective dry cow therapy] but we're about the health and we're still using Cephaguard" – Farmer

17

6.4.3.4 Decision hierarchy

Within any organisation, there is a structural hierarchy (Diefenbach, 2013). On dairy farms, this hierarchy can come in various guises. A family farm is often run by multiple generations at once, however it is recognised that there is either implicit or explicit hierarchical structure when it comes to key decision-making (Headlee, 1991). Indeed, issues surrounding succession on UK farms are a recognised area of tension on family farms.

"It's so frustrating that I want things done my way but my dad actually makes the decisions so I don't have the authority to do any managing" – **excerpt from fieldnotes, Farm A**

Conversely, on farms that employ many staff who are not immediate relations, or farms that are run by an employed farm manager, the hierarchy is far more explicit and structured.

Where a person lies within the hierarchical structure affects the treatment decisions they are able to make. Tensions emerge where a farmer feels disempowered and unable to make treatment decisions.

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

In this instance, subversive behaviour in order to achieve the desired treatment option in spite of a superior's decision was observed.

"What will eventually happen, like it has many times in the past, is that I'll go so far, and then I just lose it. Then I go off on one, and then it will get done. Or something will get done... Yeah, big time, which is annoying because that proves to me that he knew all along that it needed doing. But why wait when it's things that are affecting your cows' health? ... It is really, because if he would give me a bit more power to say, "Get on and do some of it." I wouldn't mind, but I can't at all. I know what needs doing, but he has to have the final say and he's a tight old thing, well all farmers are, aren't they? We'll get there in the end." – Farmer 8

These tensions were expressed as a source of stress to farmers. While farm managers or farmers employing staff had to navigate the trust relationship between themselves and those they managed (as described in 1.3.2.2), unless they were at the top of the hierarchical tree, they were also subject to the loss of autonomy prescribed by their superiors. These restrictions (or barriers) to treatment took many forms but most commonly were economic in nature.

"There was this cow who had E. coli. I'd been off for the weekend, came back and spotted it straight away. I asked him "why haven't you tubed her?" "We're not allowed to tube anything" he said. He wouldn't let me treat her! It's common sense, if they're that sick. You might at least get some money back if you can send them down the road [to slaughter]. If they're going to shoot her anyway may as well try to save her" – excerpt from fieldnotes: herdsman, Farm B

Here, one farm worker was chastising a fellow farm worker who was - on paper - employed at the same level. Both were acting within the same restricted structure where they had been told by their superiors not to treat animals with new cases of mastitis, but one felt greater autonomy to override

that decision than the other. This illustrates the importance of the individual's subjective interpretation of decision-making power and authority as well as the differences in behaviour that these subjectivities can induce.

6.4.4 A duty of care

The fourth and final major theme identified in this study was that of a duty of care that the farmer feels towards the animals s/he farms. This can be conceptualised across two key areas: the bovine patient and treatment as action, as outlined below. As Buller and Roe (2016, bottom of page 54) argue, animal stockpersons should be reconsidered as animal care persons. Care is inherently complex, with the care of another an "achievement alongside other demands which may be in tension with care delivery – minimising costs, personal challenges, competitive advantage – each being well-recognised characteristics of the commercial industrialised, food animal production environment."

Here this argument is furthered by suggesting that, where treatment decisions are concerned, a key motivator is a sense of duty to the wellbeing of the animals for which the participants are responsible. While care can be described as an achievement in spite of other pressures, it is also a *raison d'être* in and of itself. This 'duty of care' was at the heart of medicine use and the treatment of disease on UK dairy farms. Dairy farmer empathy is associated with animal welfare (Kielland et al., 2010) and the emergence of duty of care as one of the five key values of dairy farmers when making treatment decisions is therefore reassuring.

The value that the dairy farmer placed on the care of their animals can be examined in two key areas: the bovine patient and treatment as action. Of course, both are inextricably linked and resist separation, however, by discussing them separately it is somewhat easier to illustrate the main points of this argument.

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

6.4.4.1 *The bovine patient*

Dairy cattle (and indeed all farmed species to a greater or lesser extent) are almost entirely reliant on farmers to provide them with the basic necessities of life. Feed, water and shelter are key components of the “five freedoms” of animal welfare (Farm Animal Welfare Council, 2009); however, the most pertinent to this study is that of freedom from pain, injury or disease. Dairy cattle rely on the farmer for their physical health and wellbeing. This places the dairy cow in the position of ward, or patient, while simultaneously placing the farmer in the position of care-giver.

This sense of the ‘bovine patient’ underlies many management and husbandry practices, not least veterinary treatment decisions. While always needing to operate within the constraints of the economic, societal and political context of dairy farming, farmers see their cattle as dependents. They value the “work” that these animals do, and the income and career that they are provided by these animals’ existences and milk production.

“They’ve done us alright, you’ve got to look out for them. I’m probably just too sentimental for being a dairy farmer...” – Farmer 5

This two-way relationship between the farmer as a provider of care for the cow, and the animal as the provider of an entire way of life is appreciated in various ways. One farmer acknowledged the pleasurable lifestyle and work being afforded as attractive, while simultaneously declaring their love for the animals they work with:

“There’s a lot of benefits. You look at you’re your own boss living in a lovely area with animals that you love. It’s your own boss syndrome really. No regrets, no. I wouldn’t change it for the world.” –

Farmer 3

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

“Yeah we’re very much independent agents ... and I would like to think that we do our best to treat our animals well.” – Farmer 18

This mutually beneficial relationship between farmer and animal drives many treatment decisions on farms. A cow relies on their farmer to treat them appropriately when they are diseased. The farmer’s willingness to do this might be driven in some cases by a feeling of reciprocity. There is a sense that the farmer “owes” their animals a good life as a reward for the provision of a rewarding career and lifestyle. Indeed, for some farmers, this sense of reciprocity may lower treatment thresholds to the point that animals are treated unnecessarily, or even overdosed with PVM as a means of reward.

6.4.4.2 Treatment as action

As discussed, the health and wellbeing of the animals under the care of the farmer is extremely important to the farmer’s sense of identity as a “good farmer” and is driven by his or her duty of care to the animal. Indeed, Buller and Roe discuss the elements of self-care and maintenance of a farmer’s own wellbeing as being inextricably linked with the health and welfare of their animals.

During the participant observation fieldwork, there were examples of animals being perceived to be diseased or suffering, leading to farmers expressing feelings of distress and a desire to take action to relieve the suffering and treat the disease. Farmers have been shown to extend the duration of antimicrobial treatments because doing so made them feel like “good farmers” (Swinkels et al., 2015). This sense of treatment representing a positive action is not only serving to maintain animal health and welfare but is also self-serving in nature.

Where treatment is seen as action, veterinary medicines can be viewed as the tools for positive action in the face of disease. This can lead to over-treatment and over-medicalisation of both self-limiting disease and mis-diagnosed disease where symptoms actually lie within the ‘normal’ range for that

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

animal or herd. The concepts of overdiagnosis and medicalisation are well recognised in human medicine (van Dijk et al., 2016), and the overuse or irresponsible use of pharmaceuticals is often attributed to these phenomena (Welch et al., 2012).

In the context of veterinary medicine use on dairy farms, this concept of treatment as action can manifest in many ways. From the risk-averse behaviour inherent in the overuse of antimicrobials to the blanket use of veterinary medicines in animals that are believed to be weak unless treated:

“Every Guernsey calf has to have steroids to get it going.” – Farmer 13

While it is true that many farmers identify Guernsey calves as being smaller and less vigorous than their Friesian or Jersey counterparts at birth, this farmer had equated that with a need for corticosteroids in order to give them a ‘helping hand’ during the neonatal period. This was despite the likely negative health effects of a neonatal animal receiving corticosteroids without proven clinical need, which may or may not have been known to the farmer.

While treatment is seen as a positive action in most cases and can serve to relieve the distress associated with caring for diseased animals, the need to treat can also represent failure to some farmers:

“Well obviously I’d love a day without having to treat sick animals, a lot of people would. The thing I hate is the sick cows and having to tube cows, that is when you feel failure. But then I try to compare it by 250 humans there would be one or two going into the doctors every day wouldn’t there?” –

Farmer 3

Several farmers expressed pride when a treatment had succeeded, for example in an animal who had recovered from lameness following multiple time-consuming interventions trimming her feet to improve hoof conformation. Some also expressed frustration and shame when treatment failed to correct chronic disease and they were unable to cull, for example an animal remaining in the herd despite chronic foot problems and severe lameness. One farmer attributed a spate of healthy calves with no pneumonia or diarrhoea to luck, despite management interventions which had led to the improvement. Conversely a period of increased disease in calves was blamed on the weather, overcrowding, or other more tangible reasons on many occasions.

Worry and frustration were words that emerged frequently during this study, particularly where autonomy or knowledge were felt to be restricted. This perhaps indicates the pressure and stress that can be caused when farmers, driven by their sense of identity and a duty of care, are unable to do what they consider to be the best by their animals. If a farmer feels duty-bound to protect the health and welfare of their cows, and their entire sense of identity depends on the ability to enact this duty, it is little wonder that feelings of distress occur where a farmer does not believe they have sufficient knowledge or where they are limited in their ability to treat as they see fit.

Where antimicrobial use is concerned, farmers again expressed feelings of shame or defiance:

“Antibiotics is a dirty word isn’t it?” – Farmer 20

While often acutely aware of the drive for reduced use, these emotional factors were perceived as limiting farmers’ treatment practice and ability to do the best by their animals. The concept of “this farm” being special was again very present. There was a perception that while reducing antimicrobials in agriculture overall was conceptually beneficial, measures to improve responsible use did not necessarily apply in the context of “this farm”.

6.5 *Conclusions*

The themes that emerged during the analysis of the substantial body of data gathered during this study provide some original, empirical, qualitative evidence that significantly extends what is already known and moves it into a new domain; that of medicine use and treatment decision making. They agree with and greatly extend some of the themes reported in the existing literature and are situated within the context of medicine use. The idea of a farmer's identity influencing management decisions has been described widely in the literature on the "good farmer". When framed according to medicine-use behaviours, a farmer's belief in the uniqueness of their own farm, coupled with their professional and personal identities, form the foundation upon which treatment decisions are made.

Upon this foundation of identity lies the concept of trust. As has been described in this chapter, this trust is a liminal and relational concept that is continually renegotiated between the farmer and the 'key actors' (the veterinary surgeon, staff, animals, medicine and data). Given the continuous and reactive nature of trust, the context and culture of an individual farm is inherently unstable and vulnerable to change as the nature of these trust-relationships change. This presents a 'moving target' for industry and policy makers when trying to create any model for behaviour, even a farm-specific rather a one-size-fits-all model.

Knowledge, however, may seem a more straightforward concept in some respects. Farmers develop their own understanding of treatment and disease based on their innate knowledge and the knowledge they have acquired through experiential and experimental means. However, they are bound by the knowledge they do not have. Farmers express a frustration with these self-identified knowledge gaps and a desire to be provided with more information, specifically information about medicines. They believe that veterinary surgeons should be providing this knowledge but are currently unsatisfied with the provision of information by their veterinary surgeons. A lack of communication

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

between the veterinary profession and the farming community may explain some of this disparity and a focus on this area by both parties should be a priority in the future.

While treatment decisions are a product of the identity, trust and knowledge of the farmer, they also depend upon the farmer's autonomy, whether real or perceived. Where tensions are created between the farmer's own experience-based judgements and the ability to implement these judgements, these tensions lead to stress and worry. Conversely, where treatment autonomy is aligned with collaboratively developed protocols, the outcome is a reduction in uncertainty and, accordingly, the stress that accompanies such uncertainty.

One of the key drivers behind the treatment decisions made by the farmers in this study was their sense of having a duty of care over their animals. The cows and calves on the farm constitute domesticated dependents who rely entirely on the farmer to provide the means for their health and welfare. By using this inherent drive to care for their animals effectively, veterinary surgeons and policy makers may be able to improve animal health and welfare dramatically.

6.5.1 Study limitations

One of the most frequent criticisms of ethnography - and of qualitative social science in general - is that the data produced may be biased. The researcher (by the very nature of their presence) may influence what people say or how they act. Hence, data must be analysed and discussed reflexively, acknowledging these influences (Kuper et al., 2008). Additionally, the researcher cannot entirely exclude their own preconceptions or ideas which may influence the way they analyse the data. In the case of this study, the researcher's positionality as a veterinary surgeon may have influenced the behaviour and responses of the participants and also the analysis of the data. While the researcher (GR) did not volunteer her background as a veterinary surgeon, it would have been obvious that she had some experience in and understanding of normal dairy farming practices. Additionally, the

researcher's experiences working as a dairy veterinary surgeon will have inevitably coloured the analysis of the data.

While these criticisms make an important and valid point, as Pool and Geissler (2005) argue, social knowledge is always positional. There is no way of observing a society without having a position within it, and as such, influencing it. The authors posit that this influence is "not a methodological flaw that must be hidden, but an integral aspect of this kind of research that we should accept and make explicit in the presentation of results" (Pool and Geissler, 2005, bottom of page 17). The strength of qualitative research lies in the richness and depth of data, and the reflexivity of the researcher. This tacit knowledge can serve as a source of data, and a powerful tool for interpretation and analysis in qualitative research (Giacomini, 2001). The ethnographer's goal is not to establish "the truth", but rather to explore the multiple contextual truths that are experienced by the people being studied (Emerson et al., 2011). The positivistic view of quantitative science cannot be appropriately applied to qualitative research, and its experiential, reflective and critical nature are to its credit, not detriment (May, 2002).

During the 12-month period when research visits were taking place, participants became accustomed to the researcher's presence and the writing of fieldnotes. A friendly working relationship developed between the researcher and the participants, and in one case a key informant requested social media contact and invited the researcher to join a family dinner. In all interactions with all of the participants, the relationship was friendly, cordial and somewhat inquisitive. Although it was anticipated before the commencement of fieldwork that gaining a level of trust and respect would take time and initially responses and behaviours might have been guarded and artificial, this did not appear to be the case in practice. The researcher was welcomed very quickly on all three farms, seen as a useful addition to the working team and given some roles to carry out while undertaking the research. On more than

one occasion participants requested to see the ethnographic fieldnotes that were being written and expressed surprise at their boring nature and the interest in what they perceived to be the mundane and uninteresting day-to-day occurrences on their farms.

This research relied upon 20 semi-structured in-depth interviews and three 12-month focussed ethnographies analysed together. While this may appear to be a small sample, the selection of the farms and the study area was intended to reflect an intentionally restricted geographical and cultural area where dairy farming constituted a distinctive and coherent social and economic practice and the use of antimicrobial medicines emerged as a key component of contemporary husbandry. Twenty interviews may not represent the views of all dairy farmers, and indeed they are not intended to do so. This study aimed to describe and investigate the daily practices and values of these farmers to provide an in-depth understanding of how medicines and medicine use has become part of the infrastructure of livestock farming while reflecting what may be true for the wider population. Many qualitative studies in veterinary medicine have used fewer interviews (Vaarst et al., 2002) or very short interviews conducted by telephone (Richens et al., 2015) without the benefit of in-depth participant observation to explore farmer attitudes and perceptions. In combining a highly focused case study employing both qualitative and quantitative data, this research therefore represents a robust study within the veterinary literature.

The three farms where participant observation occurred were as unique as any farm in the UK, with their own specific contexts and cultures. This being said, each of these farms sits within the wider dairy farming context and culture of UK agriculture. The three farms on which this research focussed shared as many differences as they did similarities, and the insights gained bring a new understanding of antimicrobial use. These farms were all run by farmers who were engaged and interested in treatment outcomes and the health of their animals, while also being driven by a need to be productive and

profitable. This manifested in different ways depending on the particular farm context. For example, the small, family run farm based treatment decisions on their in-depth knowledge of each particular cow's history, temperament and subjective value to the farm, whereas the large farm with 700 dairy cows based their treatment decisions more at the herd level, and when considering individual animals would assess their value in terms of production and data analysis. These differences in the way the particular farm context affected the way in which treatment decisions were made - while still being driven by the same motivations and values as described in this chapter - present a fascinating confirmation of the importance of farm-specific context to the decision making process.

An additional challenge in this thesis has been the focus on animal patients and the treatment decisions that affect them and their welfare as well as their value. This research has drawn attention to the duty of care farmers have towards their animals as an important consideration in making treatment decisions. While it is recognised that treatment decisions for dependent domesticated animal patients are likely to draw in part upon similar concerns for health, welfare and comfort that would apply to human patients, including the participant farmers themselves, the research undertaken here did not seek to specifically explore the epistemological and methodological challenges of understanding the differences between animal and human treatment decision making. Similarly, while it is accepted that decisions relating to preventative use of medicines are likely to be driven by different considerations than those relating specifically to therapeutic uses, the empirical work in this thesis intentionally focused on treatment decision making.

6.5.2 Policy implications & future research

It became clear during the course of this research that dairy farmers in the UK do not use prescription veterinary medicines exactly as prescribed by their veterinary surgeon. Doses are increased or decreased, course lengths are altered, and medicine-choice is based on multiple factors of which

veterinary advice is but one. A US study showed that 77% of surveyed veterinary surgeons believed that dairy farmers followed protocols for antimicrobial use (Cattaneo et al., 2009) while a different study also based in the US showed that 21% of farmers had written treatment plans and less than a third consulted their veterinary surgeon prior to treating sick animals (Sawant et al., 2005). In Sweden dairy farmers' treatment decisions often differ from normal veterinary recommendations (Vaarst et al., 2002) and in the Netherlands and Germany it has become a social norm to extend antimicrobial treatment duration for mastitis (Swinkels et al., 2015). Given this dichotomy and the results of the research presented here, it follows that veterinary surgeons need to be made more aware of the actual practices occurring on farms under their care, especially given the veterinary surgeon's ultimate responsibility for the health and welfare of the animals.

There proved to be an appetite by participating farmers for more veterinary input, especially in the form of knowledge exchange, development of treatment protocols and practical, applicable herd health plans. For farmers to be able to value any treatment protocols it was necessary for them to be farm-specific and delivered in a collaborative rather than paternalistic way. While herd health planning is already a mandatory part of farm assurance schemes, policy-makers should consider improving the practical applicability of these herd health plans and encouraging collaborative development.

The development of a trusting relationship between the dairy farmer and their veterinary surgeon should be an area of focus for the veterinary profession in the UK. While other research has shown that veterinary surgeons' prescribing habits are not driven by income or profit (De Briyne et al., 2013, Gibbons et al., 2013), some farmers in this study perceived this to be the case and were consequently less likely to trust in their veterinary surgeon's advice. Future research focussing on interventions aimed at improving farmer-veterinary surgeon trust and communication as a way of improving responsible medicine use would be beneficial.

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

National control programmes have been shown to influence farmers' attitudes, knowledge and behaviour with regards to mastitis (Jansen et al., 2010); such programmes could also be useful tools for encouraging behaviour change aimed at reducing antimicrobials. Further research is needed to evaluate the impact of treatment protocols on reducing treatment uncertainty and thereby improving responsible medicine use.

More work should also be done to further investigate farmers' sense of duty of care to their animals. The effectiveness of policy interventions aimed at improving farmers' awareness of pain, disease and animal welfare indicators should be measured to determine whether, by improving recognition of poor health and welfare, farmers will alter their behaviour leading to lower treatment thresholds driven by this duty of care. Because treatments are often given by farmers, they represent positive action in the face of suffering, and therefore searching for alternative actions to that of antimicrobial use is a vital tool in the fight against AMR. It would be valuable to research whether farmers who use a more holistic approach to herd health (those who practice homeopathy or other alternative therapies, for example) have improved treatment practices purely due to the fact that they can use alternative remedies. Although scientific consensus reveals many of these therapies to be ineffective, the fact that farmers could take a positive action, allowing a disease process that would have always self-cured the time to do so and avoiding the need for antimicrobials, may be seen as a step forward. This approach, however, results in a risk of not treating animals who would require medical intervention. Seeking alternative actions and therapies where there is an evidence-base suggesting that pharmaceuticals are not required may indeed help to reduce the over-use of antimicrobials and other PVM.

Finally, there is a need for greater emphasis on participatory policy development coupled with participatory action research (using ground-up rather than top-down approaches to behaviour

Towards understanding the values of dairy farmers that influence treatment decisions and medicine-use practices

change) amongst UK dairy farmers. This type of activity takes advantage of farmers' desire to see the value in policy and research outputs, to tailor these appropriately to their own needs and, consequently, to increase their impact. As Ritter and others (2017, top of page 1) state "providing them (farmers) with rational but universal arguments might not always be sufficient to motivate on-farm change". A participatory approach, however, may be more effective at inducing genuine and lasting behaviour change in relation to responsible medicine use.

Conclusions

Conclusions

Conclusions

This thesis has explored and assessed the way that prescription veterinary medicines (PVM) are used on UK dairy farms through a mixed-methods approach. The work has considered the existing literature relating to PVM legislation, antimicrobial use and farmer behaviour, both nationally and internationally. This review of the literature identified several key knowledge gaps, which were used to formulate the research questions posed. Specifically, these knowledge gaps were the lack of quality and granularity of data available on antimicrobial use in the UK, the need for data on non-antimicrobial PVM use and the need for ethnographic study of medicine use behaviours.

The research questions developed were:

- i. How are prescription veterinary medicines being stored on UK dairy farms?
- ii. Can veterinary medicines sales data, on-farm medicine records or medicine waste bins be used to accurately estimate on-farm medicines use on study farms?
- iii. What are the values and practices of dairy farmers and what are the on-farm contexts affecting medicine use practice on UK dairy farms?

From these research questions, three key studies were designed, each using a different research methodology. The first examined the PVM storage practices on the participating farms using a cross-sectional study. The second was a method comparison study determining the levels of agreement between three different methods of recording PVM and a 'gold standard' measure. The third major study was ethnographic in nature, utilising 12 months of participant observation work on three dairy farms and combining these data with that of 20 semi-structured in-depth interviews with dairy farmers aimed at studying the values, beliefs and on-farm culture influencing PVM use.

For each of these three studies, the results are discussed in detail in their respective chapters, and specific conclusions drawn from the work are presented. In this conclusion, the results of the different chapters will be considered together. These final conclusions aim to draw on the results of all three

studies together, and to consider the broader narrative and contribution this work makes to the study of PVM and antimicrobial use in the UK.

7.1 *Summary of findings*

i. How are prescription veterinary medicines being stored on UK dairy farms?

UK dairy farmers were seen to store PVM in a broadly 'correct' way, although in varying quantities. Storage of expired and unlicensed medicines was common, and occasionally inappropriate medicines were present on farms.

ii. Can veterinary medicines sales data, on-farm medicine records or medicine waste bins be used to accurately estimate on-farm medicines use on study farms?

Veterinary sales data showed the best levels of both clinical agreement and reliability of the three medicine use measuring methods. It showed moderate or good clinical agreement and good or excellent reliability with the pre-determined gold standard for injectable and intramammary antimicrobials. Medicine waste bins showed moderate clinical agreement with the gold standard when measuring injectable antimicrobials. On-farm medicine records did not agree with the gold standard for use, and, as such, are not an effective way of reliably measuring actual PVM use.

iii. What are the values and practices of dairy farmers and the on-farm contexts affecting medicine use practice on UK dairy farms?

The answers to this research question are complex, but the study described in Chapter 6 shows that the attitudes, values and contexts most relevant to medicine use practice can be broadly divided into four dominant themes: knowledge, trust, autonomy of treatment practice and a duty of care. The way that these themes can impact on medicine use is not straightforward, and occasionally seem

contradictory. It is important, however, to realise that changing medicine use practices requires an understanding of all factors involved in treatment decisions.

The overall narrative of this thesis shows that dairy farmers store, record and use PVM in varied ways that have previously been unrecorded in the literature. While this variation did not seem to be explained by herd size, productivity or management type when visually examined, studies with greater power would be required to prove this. However, there are likely to be cultural and social reasons for the differences in medicine use practices described. The values and beliefs of dairy farmers which were manifest in this research may go some way to explaining the variations in practice observed. The on-farm context within which treatment decisions were made was also evident as a factor influencing medicine use practices, for example which member of staff was responsible for the decision and which particular animal required treatment.

These values, practices and contexts are important to inform our understanding not only of PVM treatment decisions but also to the way in which PVM are stored and the accuracy of different methods of recording use. An example of this is the low value farmers placed on the regulatory frameworks within which they must operate and the effect of these frameworks on the quality of farm medicine records being maintained. Equally, this thesis has argued that the way in which PVM are stored and recorded influences the treatment practices observed, for example resource availability having a direct impact upon treatment choice: if a medicine is not present in the medicine cupboard it is unlikely to be considered for use. The inextricable links between storage, recording and use of PVM are a key finding that has been demonstrated in this thesis.

7.2 Contribution to scientific knowledge

This thesis provides an original and necessary contribution to scientific knowledge and the body of literature on veterinary medicine use in the following ways:

Conclusions

- By demonstrating original findings which have been published in a peer-reviewed journal describing the storage of expired and unlicensed medicines on UK dairy farms, the variation in the quantities of medicines stored and the storage methods,
- By determining the levels of agreement between different veterinary medicine recording methods and a 'gold standard' for use,
- Through establishing the values, beliefs and on farm contexts influencing veterinary medicine treatment practices.

The strengths of this thesis lie in the study design – through using different methodological approaches it has been possible to examine the topic of medicines use through different lenses. Using this mixed-methods approach, it has been possible to build a rich picture of PVM use on UK dairy farms.

The three farms where participant observation was conducted can be viewed as case studies. It is not claimed that these farms are representative of all farms, however some particular insights and lessons from observation of these three farms can be taken forward. What this research is providing is threefold:

1. The development of a triangular methodology that has been tested in this particular context and can be used elsewhere, in other contexts,
2. A demonstration of how medicine use is strongly influenced by context, hence highlighting that it is critical to understand the context and the specificity of such use. This also highlights the fact that context is social, technical, economic and geographical, amongst other factors. Only by investigating and understanding the importance of this contextual variation do we come close to a genuine understanding of how medicines are used and how the different approaches to understanding use articulate with one another.

Conclusions

3. An illustration of how different ways of understanding medicine use do not always fit together nicely, and that policies and strategies based upon one particular sense of use may well fail in a different context if those designing the policies or strategies do not understand what else is going on in practice.

This being said, these case study farms are real farms using real medicines to treat real disease. They are not hypothetical or 'model' farms which represent all of dairy farming, although some of these insights can be used towards future models of treatment decision across the wider dairy farming sector. While the results derived from this study are not, and were never intended to be, generalisable across the entire industry, they can be used to develop models of behaviour and treatment decision making - including behavioural intervention work - which could be tested across the different contexts of the broader dairy farming population

The use of medicine, particularly antimicrobial treatments, being seen as almost a signalment of the "good farmer" across these three farms was, while expressed in different ways, a strong emergent narrative which was further substantiated by some of the semi-structured in-depth interviews. Similarly, during the course of the data collection it became apparent that some farms could be described as tidier than others, and that there appeared to be some form of correlation between the presentation of a farm and their use of antimicrobials. The four themes that emerged in this research can help to explain this point, and to understand how this work fits within the wider thesis when taken together with the quantitative work presented in Chapters 4 and 5.

For example, during the course of the data collection it became apparent to the researcher that some farms could be described as taking greater care in their presentation than others. When driving onto a farm for the first time, it was possible to place farms on a scale ranging from "tidy farm" to "untidy farm" based on the upkeep of the farm track (potholes/mud/cracked concrete), the organisation and layout of the farm machinery around the main yard, the presence or absence of a legible farm sign

and other such markers. While this was not objectively measured in this project as it had not formed part of the initial research questions, what appeared to emerge during data collection and subsequent analysis was that perhaps those farms which could be classed as “tidy” were more likely to have good quality medicine records, have greater compliance with medicine bin use, store their medicines in a more orderly way and have different motivations and values regarding treatment decisions than those farms which could be classed as “untidy”. Although it was not possible with the data in this thesis to directly compare the subjective “tidiness” of farms with their medicine use or farmers’ values as elicited from interview and participant observation, it is an interesting observation that warrants further research. The four themes emergent from the data in this chapter may go some way to explain this relationship: a “tidy farm” may be more engaged with external advisors and peers, gaining greater knowledge about medicine use and developing trusting relationships with veterinary surgeons and other sources of knowledge. These farms may feel they have greater autonomy of treatment practice, perhaps they are more financially secure or have more fixed succession planning in place. Additionally, there may be a link between the inherent drive to present a tidy farm to the world, and to present healthy animals to the world, as described in “a duty of care”. While this explanation is clearly speculative in nature, given the constraints of the data and the subsequent inability to fully analyse it through this lens, it does present an interesting, original research question and a rich area for future work.

The implications of the research are far-ranging, as discussed later in this chapter. The contribution this thesis makes to knowledge has been original and important, in an area of intense political and scientific focus. The knowledge gaps identified in the literature review and outlined above were used to design and implement the studies detailed in Chapters 4 – 6, which have yielded interesting and valuable results. Given the pioneering nature of this work, the results of this study can be used as an evidence base to inform policy at many levels. Additionally, these results generate many further

knowledge gaps and research questions which can be pursued in future work. These policy implications, practical applications and areas for further research are discussed below.

7.3 *Strengths and limitations of the Thesis*

The strengths and limitations of each individual study are discussed in their respective chapters; however, it is important to note some of the strengths and limitations of the thesis as a whole. Some of the key strengths can be summarised as:

- The study used mixed methodologies, combining quantitative, qualitative and ethnographic approaches, in order to establish a deep and insightful understanding of the practices of medicine use within livestock farms.
- The study enabled the identification and analysis of the values, beliefs and on-farm contexts that differentially influenced - in complex and multiple ways - the veterinary medicine treatment practices and provided insights into the potential impact of these influences.
- The positionality of the researcher as a veterinary surgeon with extensive experience of dairy cattle practice provided excellent access, compliance and easy communication between the researcher and the participants. The development of a trusting relationship was made possible in part by the researcher being able to demonstrate an aptitude for and ease with working on a dairy farm, along with technical knowledge of dairy farming and medicine treatments.
- The study provided the ability to triangulate some data between the different research studies in order to gain a further depth of understanding.

The limitations of this research can be summarised as:

- The use of purposive sampling of dairy farm participants in this thesis may introduce the potential for selection bias. However, purposive sampling in qualitative research is an accepted and

valid method, and the demographic data of the recruited farms did broadly reflect those of the UK dairy farming population.

- The positionality of the researcher as a veterinary surgeon may have influenced the behaviour and responses of the participants and also the analysis of the data. This was mitigated in so far as possible in the quantitative research by analysing the data in a positivistic way, with data validation being done by other researchers. For the qualitative data, this was achieved by adopting an informed but neutral approach, with the researcher presenting herself as a university research student without an agenda and analysing the data reflexively, accounting for the effects of positionality as described in Chapters 3 and 6.
- Prescription veterinary medicine storage practices and recording may have been influenced by the research being undertaken. Beginning the research with a PVM inventory may have had subsequent consequences on the way PVM were being used for the 12 months studied, due to the on-farm resources being an important part of treatment decision making, as described in Chapter 6. In this study, farmers were asked not to change PVM storage prior to the first visit and it was emphasised that the researcher was not there to audit their practices and report back to any legislative body but was simply interested in the real practices found on farms. Similarly, with medicine records it was emphasised that the work was designed to show what happens on real farms, not to demonstrate perfect practice. The presence of expired and unlicensed medicines across many of the study farms in Chapter 4 indicated that storage practices were unlikely to have been significantly improved as a consequence of this approach.
- It was not possible to triangulate all data across all three studies. For example, not all of the farmers who participated in the semi-structured in-depth interviews were from farms who participated in the cross-sectional study of the medicine cupboards, and not all farms that participated in the cross-sectional study were included in the method comparison study.

Conclusions

- The research took place between September 2016 and April 2018. During this time, milk prices were initially very low (below the cost of production) and then improved progressively, while the political environment was changing rapidly following the Brexit vote and the development of a post-Brexit agriculture bill. The outcomes of this research therefore may not reflect PVM use during more stable markets or during different political and cultural climates.

The nature of mixed-methods research is such that it always requires some compromise between the demands of quantitative methodologies and those of qualitative methodologies. These limitations include questions of sample size, sampling method, scientific rigour and epistemological approach. These compromises - and the justifications and precedents for the use of mixed methods - have been discussed at length in Chapter 3. Essentially, the added value of methodological pluralism through data triangulation and combined interpretation can lead to an outcome far greater than the sum of its parts.

The opportunities for further work validating and exploring that which is laid out in this thesis are discussed in the next section.

7.4 *Further work*

There are multiple opportunities for further work to continue to explore and evaluate the outcomes communicated in this thesis. The exploratory nature means that the results of this original work would benefit from further research in order to validate the findings.

By repeating the cross-sectional study of veterinary medicine cupboards on dairy farms in successive years, trends in medicine storage and use could be identified. Increasing the number of farms studied would be beneficial, as would sampling farms from a wider geographical area than that included in this thesis. By using repeated measures of medicine storage over successive years, changes in storage practices could be identified and therefore the impact of policy changes measured. This could be

particularly important given recent changes to restrict the use of HP-CIAs across the agricultural sector in the UK as outlined in Chapter 2.

Repeating the PVM measurement method comparison study across a greater number of farms distributed across the whole of the UK would help to show whether these findings are repeatable and representative of UK dairy farms. With the introduction of several new electronic medicine recording tools for farmers on the market likely in the coming years, it is important to investigate whether these new recording systems have a positive or negative effect on the reliability of the data collected. If the industry is considering moving away from the current veterinary sales data model for antimicrobial use recording towards using farm-based records - as is indicated by the piloting of a national electronic cattle medicine book - the validity of this recording method must be elucidated.

Further ethnographic work with veterinary surgeons and dairy farmers would add to the foundation developed in this thesis. For example, by conducting interviews with other key actors in the treatment decision paradigm (e.g. employed farm workers or family members with less overall decision-making authority) it would be possible to further explore the subversive treatment behaviours and organisational hierarchy identified in the participant observation work presented in Chapter 6. In addition, participant observation with prescribing veterinary surgeons and veterinary practice staff involved in dispensing these medicines and providing treatment advice to dairy farmers would yield a wealth of data that would help to further colour the picture.

In addition to furthering the work presented in this thesis, there is a need to repeat this research in different contexts and locations. The knowledge gaps identified about the use of PVM on UK dairy farms are arguably larger for smallholdings, and for beef and sheep farming. By examining the contents of medicine cupboards on these farms, exploring medicine use measures and conducting ethnographic work, it would be possible to align the knowledge base with that now available for dairy farms. By conducting similar work in other countries, it may be possible to directly compare medicine

use on UK dairy farms with those in other settings. The legislative, cultural and systematic differences between dairy farms in these countries would likely yield results that differ from those presented here. It is, however, possible that some universal truths about medicine use on farms remain, and it would be very valuable to explore this further.

7.5 *Policy implications and practical impact*

The results presented in this thesis have many implications for policy makers, industry stakeholders and the veterinary profession. As it is an under-researched area (as outlined in Chapter 2), adopting evidence-based policy is difficult with regards to PVM use. The prescription, dispensing, use and recording of PVM is a highly regulated area (again, as described in Chapter 2), however the impact of this regulation, the adherence of veterinary surgeons and dairy farmers to current legislation and the potential for targeted and meaningful behaviour change to improve responsible medicine use has been largely unknown.

The way in which PVM are being stored on dairy farms is an entirely new area of research in the UK and there has been a significant level of interest in the results of this work when disseminated to the veterinary profession and key stakeholders. The results of this work have been published in a peer-reviewed publication aimed at UK practising veterinary surgeons (Rees et al., 2018). The conclusions of this paper called for veterinary surgeons to include a medicine cupboard 'health check' in their annual herd health planning. This publication has had a direct impact on the veterinary profession: upon its publication during World Antibiotic Awareness Week 2018, the University of Bristol, the British Veterinary Association, the British Cattle Veterinary Association and the Responsible Use of Medicines in Agriculture Alliance issued press releases calling for veterinary surgeons to work with their farmers to ensure that expired and inappropriate medicines were disposed of correctly and did not remain on farms. We expect collaborative statements like this to have a lasting impact on the

Conclusions

veterinary profession and the agricultural sector, leading to more responsible use of veterinary medicines.

The differences shown between the methods of measuring PVM use also have important ramifications for the agricultural industry, milk buyers and government policy advisors. The results presented in Chapter 5 support the Veterinary Medicines Directorate's current move towards using veterinary sales data to improve data granularity with regards to antimicrobial use monitoring and provide a much-needed evidence base for this method of surveillance. Academics who use medicine waste bins now have some validation of this research method, particularly in instances where veterinary sales data is not available. Policy decisions regarding the use of on-farm medicine records for medicine use monitoring should bear in mind the results of this research which show that they do not currently reflect actual medicine use.

Given that knowledge about the way in which a medicine should be used is only part of the overall context within which a treatment decision is made, policy that focusses on knowledge transfer alone is unlikely to make a significant difference to on farm treatment practices. In fact, it seems likely that only through a combination of many different strategies aimed at different areas affecting medicine use is real and impactful change likely to be brought about. In this work, farmers expressed a desire for more formal training in responsible medicine use, and in July 2018 the Animal Medicines Best Practice programme was launched by the National Office for Animal Health in collaboration with Lantra, a provider of training and qualifications in land-based skills. This initiative aims to provide the resources for training in responsible medicines use and appears to directly answer this identified industry need. The impact of this new initiative has yet to be seen, and private veterinary practices have also begun to offer training in medicine use to farmers. Hence, this evolving picture will be in need of monitoring and re-evaluating in the future.

Conclusions

This thesis has shown that farmers desire a sense of autonomy; as such, using participatory approaches that empower farmers may be useful. Farmers need to trust their advisors and their staff, which may indicate a need for human resources and management skills training to be provided to them. The duty of care that dairy farmers feel towards their animals – which, in turn, drives the use of ‘treatment as action’ - suggests that the veterinary profession and policy makers may need to provide alternatives to antimicrobials so that farmers can still feel as if they are taking positive steps to improve the health and welfare of their animals in the face of uncertainty. Lastly, the development of treatment protocols - in collaboration with veterinary surgeons and specifically designed for their particular farm - is likely to be positively received and lead to less uncertainty and more responsible medicine use practice.

This work also shows that the experiential and experimental knowledge acquired by dairy farmers strongly affects their understanding of disease, their trust in medicine and, subsequently, their treatment decisions. While the tenets of evidence-based veterinary medicine may abhor the design of these pseudo-scientific evidence sources, rather than dismiss this as ‘bad science’, it is very important that veterinary surgeons and academia engage fully with this driver of knowledge and practice. By encouraging on-farm experimentation and drawing on the considerable practical experience of dairy farmers, it should be possible to utilise a rich source of information that can be used to improve medicine use practices. It is important to encourage ‘good science’ and critical thinking amongst farmers while also appreciating and working with the evidence that farmers hold valuable.

There are also practical implications to the research presented in this thesis. For veterinary surgeons who work with dairy farmers, key recommendations include the need to discuss PVM storage and the disposal of expired and unlicensed medicines. By utilising proactive and practical herd health planning, veterinary surgeons can improve their relationship and communication with dairy farmers, which may

Conclusions

help to increase trust and therefore make veterinary advice uptake more likely. The incorporation of a medicine cupboard 'health check' into the annual herd health plan could be very powerful, particularly if physically standing in front of the medicine cupboard and discussing the contents leads to more impactful and practical change. This would enable veterinary surgeons to identify and offer to dispose of expired medicines, discuss off-licence medicine use via the Cascade system, ensure farmers are confident knowing which medicines to use and when, and communicate any new developments or possible improvements to the current medicine use practices on the farm. The benefits of this approach would apply to the farmer - who has the opportunity and time for open communication about medicines with their veterinary surgeon – as well as be of benefit to the veterinary surgeon by increasing engagement, providing an opportunity to discuss and prescribe new medicines as appropriate, identifying any particular concerns with herd health or medicine use in general and to replacing expired medicines with newer ones.

The practical implications of these results for dairy farmers should not be understated. While influencing policy decisions, academic research and veterinary advice are key goals, the people using these medicines (the farmers themselves) are the ones ultimately affected by any recommendations made. Investing in staff management strategies to improve trust between the various actors on farm in combination with formal training in responsible medicine use and the collaborative development and use of treatment protocols are likely to have the greatest positive impact on treatment practices. Additionally, emphasising the value of accurate medicine records and practical applications of herd health advice - in combination with improved understanding of the need to remove expired and inappropriate medicines - should be the message communicated to the farming community.

With this new understanding of prescription veterinary medicine use on UK dairy farms, we can hope to collaboratively move toward a future where evidence-based, good quality data and anthropological insights inform and contribute to a more responsible use of PVM, particularly antimicrobials. This

Conclusions

objective, while ambitious, could benefit not only dairy farmers and the cows they care for but also the veterinary profession, consumers and society as a whole.

Conclusions

References

- AARESTRUP, F. M., JENSEN, V. F., EMBORG, H. D., JACOBSEN, E. & WEGENER, H. C. 2010. Changes in the use of antimicrobials and the effects on productivity of swine farms in Denmark. *American Journal of Veterinary Research*, 71, 726-733.
- ABOU-AUDA, H. S. 2002. An Economic Assessment of the Extent of Medication Use and Wastage Among Families in Saudi Arabia and Arabian Gulf Countries. *Clinical Therapeutics*, 25.
- AGRICULTURE AND HORTICULTURE DEVELOPMENT BOARD 2016. Dairy statistics: an insider's guide. *AHDB Dairy 2016 Dairy Statistics*.
- AGRICULTURE AND HORTICULTURE DEVELOPMENT BOARD. 2018. *What is AHDB Dairy* [Online]. <https://dairy.ahdb.org.uk/about-ahdb-dairy/what-is-ahdb-dairy/#.XBZOxNv7Spo>. [Accessed 1st December 2018 2018].
- AHDB PORK 2018. eMB Pigs. <https://emb-pigs.ahdb.org.uk/>: AHDB Pork. [Accessed 1st December 2018]
- AIVALLI, P. K., ELIAS, M. A., PATI, M. K., BHANUPRAKASH, S., MUNEGOWDA, C., SCHROFF, Z. C. & SRINIVAS, P. N. 2018. Perceptions of the quality of generic medicines: implications for trust in public services within the local health system in Tumkur, India. *BMJ Global Health*, 2.
- AJZEN, I. 1991. THE THEORY OF PLANNED BEHAVIOR. *Organizational Behavior and Human Decision Processes*, 50, 179-211.
- AJZEN, I. 2015. The theory of planned behaviour is alive and well, and not ready to retire: a commentary on Sniehotta, Presseau, and Araujo-Soares. *Health Psychology Review*, 9, 131-137.
- ALARCON, P., WIELAND, B., MATEUS, A. L. P. & DEWBERRY, C. 2014. Pig farmers' perceptions, attitudes, influences and management of information in the decision-making process for disease control. *Preventive Veterinary Medicine*, 116, 223-242.
- ARLAGÅRDEN 2017. Arlagården standards. 1st July 2017 ed. <https://www.arlafoods.co.uk/4a3b63/globalassets/arla-global/company---overview/responsibility/pdf/quality-assurance-programme/standards---updated-from-1-january-2017.pdf>. [Accessed 1st December 2018]
- ATWOOD-HARVEY, D. 2003. *Interspecies Encounters: An Ethnography of a Veterinary Hospital*. PhD, Western Michigan University.
- BAILEY, A. P. & GARFORTH, C. 2014. An industry viewpoint on the role of farm assurance in delivering food safety to the consumer: the case of the dairy sector of England and Wales. *Food Policy*, 45, 14-24.
- BARBOSA, C. D., BALP, M. M., GERMAIN, N. & ROFAIL, D. 2012. A literature review to explore the link between treatment satisfaction and adherence, compliance and persistence. *Patient preference and adherence*, 6, 39-48
- BARD, A. M. 2018. *Improving dairy cattle welfare: examining Motivational Interviewing, veterinary communication and the herd health advisory paradigm*. Doctor of Philosophy, Univerisiy of Bristol.
- BARD, A. M., MAIN, D. C. J., HAASE, A. M., WHAY, H. R., ROE, E. J. & REYHER, K. K. 2017. The future of veterinary communication: Partnership or persuasion? A qualitative investigation of veterinary communication in the pursuit of client behaviour change. *PLOS One*, Published online: March 3, 2017.
- BASIT, T. 2010. Manual or electronic? The role of coding in qualitative data analysis. *Educational Research*, 45, 143-154

Formatted: German (Germany)

Field Code Changed

Formatted: German (Germany)

- BECKER, H. S., GEER, B., HUGHES, E. C. & STRAUSS, A. L. 1961. *Boys in White: Student Culture in Medical School*, USA, Transaction Publishers.
- BEEDELL, J. & REHMAN, T. 2000. Using social-psychology models to understand farmers' conservation behaviour. *Journal of Rural Studies*, 16, 117-127.
- BERGEA, H., ROTH, A., EMAUNELSON, U. & AGENAS, S. 2016. Farmer awareness of cow longevity and implications for decision-making at farm level. *Acta Agriculturae Scandinavica, Section A — Animal Science*, 66, 25-34.
- BIGGS, S. D. 1990. A multiple source of innovation model of agricultural research and technology promotion. *World Development*, 18 (11), 1481-1499.
- BIRKHAUER, J., BAAB, J., KOSSOWSKY, J., HASLER, S., KRUMMENACHER, P., WERNER, C. & GERGER, H. 2017. Trust in the health care professional and health outcome: A meta-analysis. *PLOS One*, Published online February 7, 2017.
- BLAND, J. M. & ALTMAN, D. G. 1986. Statistical methods for assessing agreement between two methods of clinical assessment. *Lancet*, 8, 307-310.
- BLAND, J. M. & ALTMAN, D. G. 1999. Measuring agreement in method comparison studies. *Statistical Methods in Medical Research*, 8, 135-60.
- BONDT, N., JENSEN, V. F., PUISTER-JANSEN, L. F. & VAN GEIJLSWIJK, I. M. 2013. Comparing antimicrobial exposure based on sales data. *Preventive Veterinary Medicine*, 108, 10-20.
- BORKAN, J. M. 204. Mixed Methods Studies: A Foundation for Primary Care Research. *Annals of Family Medicine*, 2(1), 4-6.
- BORRIELLO, S. P. & SHARLAND, M. 2015. Joint report on human and animal antibiotic use, sales and resistance, 2013. *UK One Health Report*.
- BOS, M. E., MEVIUS, D. J., WAGENAAR, J. A., VAN GEIJLSWIJK, I. M., MOUTON, J. W., HEEDERIK, D. J. & NETHERLANDS VETERINARY MEDICINES, A. 2015. Antimicrobial prescription patterns of veterinarians: introduction of a benchmarking approach. *Journal of Antimicrobial Chemotherapy*, 70, 2423-5.
- BRANDTH, B. 2006. *Embodying family farm work*, Rural Gender Relations: Issues and case studies, Cabi Publishing.
- BRAUN, V. & CLARKE, V. 2006. Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3, 77-101.
- BRAUN, V. & CLARKE, V. 2014. What can "thematic analysis" offer health and wellbeing researchers? *International Journal of Qualitative Studies on Health and Wellbeing*, 9, 26152.
- BRENNAN, N., BARNES, R., CALNAN, M., CORRIGAN, O., DIEPPE, P. & ENTWISTLE, V. 2013. Trust in the health-care provider-patient relationship: a systematic mapping review of the evidence base. *International Journal for Quality in Health Care*, 25 (6), 682-688.
- BRITISH BROADCASTING CORPORATION. 2005. Countryfile exposes illegal selling of animal drugs. *BBC Press Office*.
- BRITISH CATTLE VETERINARY ASSOCIATION 2017. BCVA promotes responsible use of antimicrobials. *Veterinary Record*, 180.
- BRITISH CATTLE VETERINARY ASSOCIATION. 2018. *Milksure: A training course for farmers to avoid medicine residues in milk* [Online]. <https://milksure.co.uk/>. [Accessed 12th May 2018].
- BRITISH SMALL ANIMAL VETERINARY ASSOCIATION 2017. BSAVA Guide to the Use of Veterinary Medicines. <https://www.bsava.com/Resources/Veterinary-resources/Medicines-Guide/Supplying-and-dispensing-procedures>. [Accessed 1st December 2018]
- BRITISH VETERINARY ASSOCIATION 2015. Responsible use of antimicrobials in veterinary practice: The 7 point plan. https://www.bva.co.uk/uploadedFiles/Content/News_campaigns_and_policies/Policies/Medicines/BVA_Antimicrobials_Poster.PDF. [Accessed 1st December 2018]

- BROOM, A., BROOM, J. & KIRBY, E. 2014. Cultures of resistance? A Bourdieusian analysis of doctors' antibiotic prescribing. *Social Science and Medicine*, 110, 81-88.
- BRYMAN, A. 2006. Integrating quantitative and qualitative research: how is it done? *Qualitative Research*, 6(11), 97-113.
- BRYMAN, A. 2008. *Social Research Methods*, Oxford, UK, Oxford University press.
- BULLER, H., HINCHLIFFE, S., HOCKENHULL, J., BARRETT, D. C., REYHER, K. K., BUTTERWORTH, A. & HEATH, C. 2015. Systematic review and social research to further understanding of current practice in the context of using antimicrobials in livestock farming and to inform appropriate interventions to reduce antimicrobial resistance within the livestock sector. *DEFRA Report*.
- BULLER, H. & ROE, E. 2016. *Food and Animal Welfare*, UK, Bloomsbury.
- BURTON, R. J. F. 2004. Reconceptualising the 'behavioural approach' in agricultural studies: a socio-psychological perspective. *Journal of Rural Studies*, 20, 359-371.
- BURTON, R. J. F., PEOPLES, S. & COOPER, M. H. 2012. Building 'cowshed cultures': A cultural perspective on the promotion of stockmanship and animal welfare on dairy farms. *Journal of Rural Studies*, 28, 174-187.
- BUSTON, K. 1997. NUD*IST in Action: Its use and its Usefulness in a Study of Chronic Illness in Young People. *Sociological Research Online*, 2(3), 1-13.
- BUTLER, J. K. 1986. Reciprocity of Trust between Professionals and Their Secretaries. *Psychological Reports*, 53(2), 411-416.
- CABRAL, C., LUCAS, P. J., INGRAM, J., HAY, A. D. & HORWOOD, J. 2015. "It's safer to..." parent consulting and clinician antibiotic prescribing decisions for children with respiratory tract infections: An analysis across four qualitative studies. *Social Science & Medicine*, 136-137, 156-64.
- CAMPBELL, J. L., QUINCY, C., OSSERMAN, J. & PEDERSEN, O. K. 2013. Coding In-depth Semistructured Interviews: Problems of Unitization and Inter-coder Reliability and Agreement. *Sociological Methods & Research*, 42(3), 294-320.
- CANTRALL, L., SUCHARD, J. R., WU, A. & GERONA, R. R. 2012. Stability of Active Ingredients in Long-Expired Prescription Medicines. *Archives of Internal Medicine*, 172(21), 1685-1687.
- CARDOSO, J. R., PEREIRA, L. M., IVERSEN, M. D. & RAMOS, A. L. 2014. What is gold standard and what is ground truth? *Dental Press Journal of Orthodontics*, 19, 27-30.
- CARNEVALE, R. A. & SHRYOCK, T. R. 2006. Animal health pharmaceutical industry. *Preventive Veterinary Medicine*, 73, 217-220.
- CARR, J. & SMITH, J. 2013. Storage and safe use of medicines on farm. *In Practice*, 35, 36-42.
- CATTANEO, A. A., WILSON, R., DOOHAN, D. & LEJEUNE, J. T. 2009. Bovine veterinarians' knowledge, beliefs, and practices regarding antibiotic resistance on Ohio dairy farms. *Journal of Dairy Science*, 92, 3494-3502.
- CHAUVIN, C., MADEC, F., GUILLEMOT, D. & SANDERS, P. 2001. The crucial question of standardisation when measuring drug consumption. *Veterinary Research*, 32, 533-543.
- CHRISTLEY, R. M. & PERKINS, E. 2010. Researching hard to reach areas of knowledge: qualitative research in veterinary science. *Equine Veterinary Journal*, 42, 285-6.
- CITY AND GUILDS 2017. Level 2 Certificate of Competence in the Safe and Responsible Use of Veterinary Medicines. January 2017 ed. [file:///C:/Users/gr14229/Chrome%20Local%20Downloads/0141L 2 COC in the Safe and Responsible Use of Veterinary Medicines Handbook%20v1-2%20pdf.pdf](file:///C:/Users/gr14229/Chrome%20Local%20Downloads/0141L%20COC%20in%20the%20Safe%20and%20Responsible%20Use%20of%20Veterinary%20Medicines%20Handbook%20v1-2%20pdf.pdf): City & Guilds. [Accessed 1st December 2018]
- CLAASEN, J. A. H. R. 2005. The gold standard: not a golden standard. *BMJ* 330(7500), 1121.
- COCKCROFT, P. D. & HOLMES, M. 2003. *Handbook of evidence-based veterinary medicine*, UK, Wiley-Blackwell.

- CORBIN, J. & STRAUSS, A. L. 2015. *Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory*, USA, SAGE Publishing.
- COSTELLO, J. 2001. Nursing older dying patients: findings from an ethnographic study of death and dying in elderly care wards. *Journal of Advanced Nursing*, 35(1), 59-68.
- COSTELLOE, C., METCALFE, C., LOVERING, A., MANT, D. & HAY, A. D. 2010. Effect of antibiotic prescribing in primary care on antimicrobial resistance in individual patients: systematic review and meta-analysis. *BMJ*, 340, c2096.
- COURTNEY, B., EASTON, J., INGLESBY, T. V. & SOOHOO, C. 2009. Maximizing State and Local Medical Countermeasure Stockpile Investments through the Shelf-Life Extension Program. *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 7(1), 101-107.
- COYNE, L. A., PINCHBECK, G. L., WILLIAMS, N. J., SMITH, R. F., DAWSON, S., PEARSON, R. B. & LATHAM, S. M. 2014. Understanding antimicrobial use and prescribing behaviours by pig veterinary surgeons and farmers: a qualitative study. *Veterinary Record*, 175, 593-593.
- CRITCHLEY, W. R. S. 2000. Inquiry, initiative and inventiveness: Farmer innovators in East Africa. *Physics and Chemistry of the Earth, Part B: Hydrology, Oceans and Atmosphere*, 25(3), 285-288.
- DAVIES, P., REMNANT, J. G., GREEN, M. J., GASCOIGNE, E., GIBBON, N., HYDE, R., PORTEOUS, J. R., SCHUBERT, K., LOVATT, F. & CORBISHLEY, A. 2017. Quantitative analysis of antibiotic usage in British sheep flocks. *Vet Rec*, 181, 511.
- DE BRIYNE, N., ATKINSON, J., POKLUDOV, L., BORRIELLO, S. P. & PRICE, S. 2013. Factors influencing antibiotic prescribing habits and use of sensitivity testing amongst veterinarians in Europe. *Veterinary Record*, 173, 475.
- DE CRAEN, A. J., ROOS, P. J., DE VRIES, A. L. & KLEIJNEN, J. 1996. Effect of colour of drugs: systematic review of perceived effect of drugs and of their effectiveness. *BMJ*, 313(7072), 1624-1626.
- DE ROSA, M. & TRABALZI, F. 2016. Everybody does it, or how illegality is socially constructed in a southern Italian food network. *Journal of Rural Studies*, 45, 303-311.
- DEPARTMENT FOR ENVIRONMENT FISHERIES AND RURAL AFFAIRS 2018. Agriculture in the UK 2017. <https://www.gov.uk/government/statistics/agriculture-in-the-united-kingdom-2017>. [Accessed 12th December 2018]
- DERNBURG, A. R., FABRE, J., PHILIPPE, S., SULPICE, P. & CALAVAS, D. 2007. A study of the knowledge, attitudes, and behaviors of french dairy farmers toward the farm register. *Journal of Dairy Science*, 90, 1767-1774.
- DICICCO-BLOOM, B. & CRABTREE, B. F. 2006. The qualitative research interview. *Medical Education*, 40, 314-21.
- DIEFENBACH, T. 2013. *Hierarchy and Organisation: Towards a General Theory of Hierarchical Social Systems*, New York, Routledge.
- DUNNE, S. S. & DUNNE, C. P. 2015. What do people really think of generic medicines? A systematic review and critical appraisal of literature on stakeholder perceptions of generic drugs. *BMC Medicine*, 13, 173.
- DURST, P. T., MOORE, S. J., RITTER, C. & BARKEMA, H. W. 2018. Evaluation by employees of employee management on large US dairy farms. *J Dairy Sci*, 101, 7450-7462.
- EDWARDS-JONES, G. 2006. Modelling farmer decision-making: concepts, progress and challenges. *Animal Science*, 82, 783-790.
- ELLIS-IVERSEN, J., COOK, A. J., WATSON, E., NIELEN, M., LARKIN, L., WOOLDRIDGE, M. & HOGEVEEN, H. 2010. Perceptions, circumstances and motivators that influence implementation of zoonotic control programs on cattle farms. *Prev Vet Med*, 93, 276-85.
- ELM, E. V., ALTMAN, D. G., EGGER, M., POCOCK, S. J., GÖTZSCHE, P. C. & VANDENBROUCKE, J. P. 2008. The Strengthening the Reporting of Observational Studies in Epidemiology

- (STROBE)statement: guidelines for reporting observational studies. *Journal of Clinical Epidemiology*, 61, 344-9.
- EMERSON, R. M., FRETZ, R. I. & SHAW, L. L. 2011. *Writing Ethnographic Fieldnotes*, Chicago, USA, The University of Chicago Press, Ltd.
- ENTICOTT, G., MAYE, D., CARMODY, P., NAYLOR, R., WARD, K., HINCHLIFFE, S., WINT, W., ALEXANDER, N., ELGIN, R., ASHTON, A., UPTON, P., NICHOLSON, R., GOODCHILD, T., BRUNTON, L. & BROUGHAN, J. 2015. Farming on the edge: farmer attitudes to bovine tuberculosis in newly endemic areas. *Veterinary Record*, 177, 439.
- ENTICOTT, G. P. 2012. The Local Universality of Veterinary Expertise and the Geography of Animal Disease. *Transactions of the Institute of British Geographers*, 37, 75-88.
- ESCOBAR, M. 2015. DEFRA Report: Perceptions and practices of farm record-keeping and their implications for animal welfare and regulation. *DEFRA Report*.
- ESCOBAR, M. & BULLER, H. 2014. Projecting Social Science into Defra's evidence base 2014: A review of current research and evidence gaps on the issue of farmer behaviour with respect to animal welfare. *DEFRA Report*.
- ESCOBAR, M. P. D., D. 2016. Paperwork and the decoupling of audit and animal welfare: The challenges of materiality for better regulation. *Environment and Planning C: Government and Policy*, 0, 1-22.
- EUROPEAN MEDICINES AGENCY 1999. ICH Topic Q 6 B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products In: EMA (ed.). http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002824.pdf. [Accessed 12th December 2018]
- EUROPEAN MEDICINES AGENCY 2001. Note for guidance on in-use stability testing of veterinary medicinal products (excluding immunological veterinary medicinal products) In: EMA (ed.). http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004399.pdf: EMA.
- EUROPEAN MEDICINES AGENCY 2003. I[Accessed 12th December 2018]CH Topic Q 1 A (R2) Stability Testing of new Drug Substances and Products In: EMA (ed.). http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002651.pdf. [Accessed 12th December 2018]
- EUROPEAN MEDICINES AGENCY 2011. Reflection paper on the use of macrolides, lincosamides and streptogramins (MLS) in food-producing animals in the European Union: development of resistance and impact on human and animal health. In: USE, C. F. M. P. F. V. (ed.). <https://www.ema.europa.eu/documents/scientific-guideline/reflection-paper-use-macrolides-lincosamides-streptogramins-mls-food-producing-animals-european-en-0.pdf>. [Accessed 12th December 2018]
- EUROPEAN MEDICINES AGENCY 2014. Answers to the requests for scientific advice on the impact on public health and animal health of the use of antibiotics in animals. <https://www.ema.europa.eu/documents/other/answers-requests-scientific-advice-impact-public-health-animal-health-use-antibiotics-animals-en.pdf>. [Accessed 12th December 2018]
- EUROPEAN MEDICINES AGENCY 2017. Sales of veterinary antimicrobial agents in 30 European countries in 2016. In: ESVAC (ed.). <https://www.ema.europa.eu/documents/report/sales-veterinary-antimicrobial-agents-30-european-countries-2016-trends-2010-2016-eighth-esvac-en.pdf>. [Accessed 12th December 2018]
- EUROPEAN MEDICINES AGENCY. 2018. *EMA Homepage* [Online]. <https://www.ema.europa.eu/>. [Accessed 12th December 2018].
- EUROPEAN UNION 2009. Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin In: COMMISSION, E. (ed.).

- <https://publications.europa.eu/en/publication-detail/-/publication/97469e42-8ef3-4536-86bd-46ef667e8a3d/language-en>. [Accessed 12th December 2018]
- FARM ANIMAL WELFARE COUNCIL 2009. FAWC Report on Farm Animal Welfare in Great Britain: Past, Present and Future. <https://www.gov.uk/government/publications/fawc-report-on-farm-animal-welfare-in-great-britain-past-present-and-future>. [Accessed 1st December 2018]
- FARRINGTON, J. & MARTIN, A. M. 1988. Farmer participatory research: A review of concepts and recent fieldwork. *Agricultural Administration and Extension*, 29(4), 247-264.
- FERNER, C., OBRITZHAUSER, W., FUCHS, K. & SCHMEROLD, I. 2014. Development and evaluation of a system to assess antimicrobial drug use in farm animals: results of an Austrian study. *Veterinary Record*, 175(17), 429.
- FIRTH-COZENS, J. 2004. Organisational trust: the keystone to patient safety. *Quality and Safety in Health Care*, 13, 56-61.
- FISHBEIN, M. & AJZEN, I. 1975. Belief, Attitude, intention and Behaviour: An Introduction to Theory and Research. *Addison-Wesley, Reading M.A.*
- FISHER, R. K. 2013. 'A gentleman's handshake': The role of social capital and trust in transforming information into usable knowledge. *Journal of Rural Studies*, 31, 13-22.
- FOSS, C. & ELLEFSEN, B. 2002. The value of combining qualitative and quantitative approaches in nursing research by means of method triangulation. *Journal of Advanced Nursing*, 40(2), 242-248.
- GARFORTH, C. 2015. Livestock Keepers' Reasons for Doing and Not Doing Things Which Governments, Vets and Scientists Would Like Them to Do. *Zoonoses and Public Health*, 62, 29-38.
- GARFORTH, C., MCKEMEY, K., REHMAN, T., TRANTER, R., COOKE, R., PARK, J., DORWARD, P. & YATES, C. 2006. Farmers' attitudes towards techniques for improving oestrus detection in dairy herds in South West England. *Livestock Science*, 103, 158-168.
- GARFORTH, C. & REHMAN, T. 2006. Research to understand and model the behaviour and motivations of farmers in responding to policy changes (England). (Project Report No.9). *Research to understand and model the behaviour and motivations of farmers in responding to policy changes*, 485.
- GARFORTH, C. J., BAILEY, A. P. & TRANTER, R. B. 2013. Farmers' attitudes to disease risk management in England: A comparative analysis of sheep and pig farmers. *Preventive Veterinary Medicine*, 110, 456-466.
- GASSON, R. 1973. GOALS AND VALUES OF FARMERS. *Journal of Agricultural Economics*, 24, 521-542.
- GAZMARARIAN, J. A., WILLIAMS, M. V., PEEL, J. & BAKER, D. W. 2003. Health literacy and knowledge of chronic disease. *Patient Education and Counselling*, 51(3), 267-275.
- GIACOMINI, M. K. 2001. The rocky road: qualitative research as evidence [EBM Note]. *Evidence Based Medicine*, 6, 4-6.
- GIBBENS, N. 2016. Antibiotic Resistance: in the news and staying there. *Veterinary Record*, 178.
- GIBBONS, J. F., BOLAND, F., BUCKLEY, J. F., BUTLER, F., EGAN, J., FANNING, S., MARKEY, B. K. & LEONARD, F. C. 2013. Influences on antimicrobial prescribing behaviour of veterinary practitioners in cattle practice in Ireland. *Veterinary Record*, 172(1), 14+.
- GILSON, L. 2003. Trust and the development of health care as a social institution. *Social Science and Medicine*, 56(7), 1453-1468.
- GLASER, B. G. & STRAUSS, A. L. 1999. *Discovery of Grounded Theory*, New York, USA, Routledge.
- GOFFMAN, E. 1961. *Asylums: Essays on the Condition of the Social Situation of Mental Patients and Other Inmates*, US, Anchor Books.
- GONZALEZ PEREYRA, V., POL, M., PASTORINO, F. & HERRERO, A. 2015. Quantification of antimicrobial usage in dairy cows and preweaned calves in Argentina. *Preventive Veterinary Medicine*, 122(3), 273-279.

- GOODSON, L. & VASSAR, M. 2011. An overview of ethnography in healthcare and medical education research. *Journal of Educational Evaluation for Health Professionals*, 8, 4.
- GOOLD, S. D. 2002. Trust, distrust and Trustworthiness: Lessons from the Field. *Journal of General Internal Medicine*, 17(1), 79-81.
- GREEN, J. B., N. 1998. Qualitative research and evidence based medicine. *BMJ*, 316, 1230-1232.
- GREENHALGH, T. 2017. Adjuvant chemotherapy: an autoethnography. *Subjectivity*, 10(4), 340-357.
- GUNN, G. J., HEFFERNAN, C., HALL, M., MCLEOD, A. & HOVI, M. 2008. Measuring and comparing constraints to improved biosecurity amongst GB farmers, veterinarians and the auxiliary industries. *Preventive Veterinary Medicine*, 84, 310-23.
- HALL, J. & WAPENAAR, W. 2012. Opinions and practices of veterinarians and dairy farmers towards herd health management in the UK. *Veterinary Record*, 170, 441-U49.
- HAMMERSLEY, M. & ATKINSON, P. 2007. *Ethnography: Principles in Practice*, UK, Routledge.
- HAUG, A., STENTOFT ARLBJØRN, J., ZACHARIASSEN, F. & SCHLICHTER, J. 2013. Master data quality barriers: an empirical investigation. *Industrial Management & Data Systems*, 113, 234-249.
- HAVERKORT, B. 1991. *Joining Farmers' Experiments: Experiences in Participatory Technology Development*, UK, ITDG Publishing.
- HAWKINGS, N. J., BUTLER, C. C. & WOOD, F. 2008. Antibiotics in the community: a typology of user behaviours. *Patient Educ Couns*, 73, 146-52.
- HEADLEE, S. 1991. *The Political Economy of a Family Farm*, New York, Praeger.
- HEALTH AND SAFETY EXECUTIVE. 2012. *Veterinary medicines: Safe use by farmers and other animal handlers* [Online]. <http://www.hse.gov.uk/pubns/as31.htm>. [Accessed May 25, 2018].
- HEKTOEN, L. 2004. Investigations of the motivation underlying Norwegian dairy farmers' use of homeopathy. *Veterinary Record*, 155, 701-7.
- HESSE-BIBER, S. & LEAVY, P. L. 2010. *The Practice of Qualitative Research*, UK, SAGE Publications.
- HIGHAM, L. E., DEAKIN, A., TIVEY, E., PORTEUS, V., RIDGWAY, S. & RAYNER, A. C. 2018. A survey of dairy cow farmers in the United Kingdom: knowledge, attitudes and practices surrounding antimicrobial use and resistance. *Veterinary Record*, 183, 746.
- HILL, A. E., GREEN, A. L., WAGNER, B. A. & DARGATZ, D. A. 2009. Relationship between herd size and annual prevalence of and primary antimicrobial treatments for common diseases on dairy operations in the United States. *Preventive Veterinary Medicine*, 88, 264-277.
- HILLERTON, J. E., IRVINE, C. R., BRYAN, M. A., SCOTT, D. & MERCHANT, S. C. 2016. Use of antimicrobials for animals in New Zealand, and in comparison with other countries. *New Zealand Veterinary Journal*, 65(2), 71-77.
- HOFFMAN, V., PROBST, K. & CHRISTINCK, A. 2007. Farmers and researchers: How can collaborative advantages be created in participatory research and technology development? *Agriculture and Human Values*, 24(3), 355-368.
- HOLDEN, J. & BOWER, P. 1998. How does misuse of the term "Hawthorne Effect" affect the interpretation of research outcomes? *Journal of Health Services Research and Policy*, 3, 192.
- HOLLOWAY, I. 1997. *Basic Concepts for Qualitative Research*, UK, Wiley-Blackwell.
- HOLLOWAY, L., BEAR, C. & WILKINSON, K. 2014. Re-capturing bovine life: Robot-cow relationships, freedom and control in dairy farming. *Journal of Rural Studies*, 33, 131-140.
- HOQUE, Z., COVALESKI, M. A. & GOONERATNE, T. N. 2013. Theoretical triangulation and pluralism in research methods in organizational and accounting research. *Accounting, Auditing & Accountability Journal*, 26(7), 1170-1198.
- HORSEMAN, S., ROE, E., HUXLEY, J., BELL, N., MASON, C. & WHAY, H. R. 2014. The use of in-depth interviews to understand the process of treating lame dairy cows from the farmers' perspective. *Animal Welfare*, 23(2), 157-165.

- HORWOOD, J., CABRAL, C., HAY, A. D. & INGRAM, J. 2016. Primary care clinician antibiotic prescribing decisions in consultations for children with RTIs: a qualitative interview study. *British Journal of General Practice*, 66(644), 207-213.
- HOWE, K. R. 1988. Against the Quantitative-Qualitative Incompatibility Thesis or Dogmas Die Hard. *Educational Researcher*, 17(8), 10-16.
- HYDE, R. M., REMNANT, J. G., BRADLEY, A. J., BREEN, J. E., HUDSON, C. D., DAVIES, P. L., CLARKE, T., CRITCHELL, Y., HYLANDS, M., LINTON, E., WOOD, E. & GREEN, M. J. 2017. Quantitative analysis of antimicrobial use on British dairy farms. *Veterinary Record*, 181, 683.
- INGOLD, T. 2000. *From Trust to Domination: an alternative history of human-animal relations*, London, Routledge.
- INGRAM, J., CABRAL, C., HAY, A. D., LUCAS, P. J. & HORWOOD, J. E. A. 2013. Parents' information needs, self-efficacy and influences on consulting for childhood respiratory tract infections: a qualitative study. *BMC Family Practice*, 14, 106.
- JANSEN, J., VAN SCHAİK, G., RENES, R. J. & LAM, T. 2010. The effect of a national mastitis control program on the attitudes, knowledge, and behavior of farmers in the Netherlands. *Journal of Dairy Science*, 93, 5737-5747.
- JANZ, N. K. & BECKER, M. H. 1984. THE HEALTH BELIEF MODEL - A DECADE LATER. *Health Education Quarterly*, 11, 1-47.
- JARVIS, L. S. & VALDES-DONOSO, P. 2015. A Selective Review of the Economic Analysis of Animal Health Management. *Journal of Agricultural Economics*, 69(1), 201-225.
- JENKINS, T. C., TIRWIN, A., COOMBS, L., DEALLEUAME, L., ROSS, S. E., ROZWADOWSKI, J., WEBSTER, B., DICKINSON, L. M., SABEL, A. L., MACKENZIE, T. D., WEST, D. R. & PRICE, C. S. 2013. Effects of Clinical Pathways for Common Outpatient Infections on Antibiotic Prescribing. *The American Journal of Medicine*, 126(4), 327-335.
- JOHNSON, R. B. & ONWUEGBUZIE, A. J. 2004. Mixed Methods Research: A Research Paradigm Whose Time Has Come. *Educational Researcher*, 33(7), 14-26.
- JONES, J. S., J. 2017. Ethnography: Challenges and Opportunities. *BMJ Evidence Based Nursing*, 20, 98-100.
- JONES, P. J., MARIER, E. A., TRANTER, R. B., WU, G., WATSON, E. & TEALE, C. J. 2015. Factors affecting dairy farmers' attitudes towards antimicrobial medicine usage in cattle in England and Wales. *Preventive Veterinary Medicine*, 121, 30-40.
- JONES, S., HOLDSWORTH, S. & KENDALL, H. 2004. Ways for prescribing to be measured. *The Pharmaceutical Journal*, 272, 58-60.
- KALER, J. & GREEN, L. E. 2013. Sheep farmer opinions on the current and future role of veterinarians in flock health management on sheep farms: A qualitative study. *Preventive Veterinary Medicine*, 112(3-4), 370-377.
- KATUSIIME, B., CORLETT, S., REEVE, J. & KRŠKA, J. 2016. Measuring medicine-related experiences from the patient perspective: a systematic review. *Patient Related Outcome Measures*, 7, 157-171.
- KAUPINEN, T., VAINIO, A., VALROS, A., RITA, H. & VESALA, K.M. 2010. Improving animal welfare: qualitative and quantitative methodology in the study of farmers' attitudes. *Animal Welfare*, 19, 523-536.
- KAWULICH, B. 2005. Participant Observation as a Data Method. *Forum: Qualitative Social Research*, 6(2), 43.
- KIELLAND, C., SKJERVE, E., OSTERAS, O. & ZANELLA, A. J. 2010. Dairy farmer attitudes and empathy toward animals are associated with animal welfare indicators. *Journal of Dairy Science*, 93, 2998-3006.
- KINGSHAY. 2018. *Kingshay: About* [Online]. <https://www.kingshay.com/>. [Accessed 12th December 2018].

- KNIGHT, J. 2005. *Animals in Person: Cultural Perspectives on Human-Animal Intimacy*, Oxford, UK, Bergman.
- KOO, T. K. & LI, M. Y. 2016. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. *Journal of Chiropractic Medicine*, 15(2), 155-163.
- KRAMER, T., JANSEN, L. E., LIPMAN, L. J. A., SMIT, L. A. M., HEEDERIK, D. J. J. & DORADO-GARCIA, A. 2017. Farmers' knowledge and expectations of antimicrobial use and resistance are strongly related to usage in Dutch livestock sectors. *Preventive Veterinary Medicine*, 147, 142-148.
- KRISTENSEN, E. & JAKOBSEN, E. B. 2011. Danish dairy farmers' perception of biosecurity. *Preventive Veterinary Medicine*, 99, 122-129.
- KUHN, T. S. 1962. *The Structure of Scientific Revolutions*, Chicago, USA, The University of Chicago.
- KUPER, A., LINGARD, L. & LEVINSON, W. 2008. Critically appraising qualitative research. *BMJ*, 337, a1035.
- LAFLEUR, J. & ODERDA, G. M. 2004. Methods to measure patient compliance with medication regimens. *HJournal of Pain and Palliative Care Pharmacotherapy*, 18(3), 81-87.
- LAMBERT, H. & MCKEVITT, C. 2002. Anthropology in health research: from qualitative methods to multidisciplinary. *BMJ*, 325(7357), 210-213.
- LEWIS, J. D. & WIEGART, A. 1985. Trust as a Social Reality. *Social Forces*, 63(4), 967-985.
- LEWIS, P. J. & TULLY, M. P. 2009. Uncomfortable prescribing decisions in hospitals: the impact of teamwork. *Journal of the Royal Society of Medicine*, 102, 8.
- LIAMPUTTONG, P. & EZZY, D. 2005. *Qualitative Research Methods*, Oxford, Oxford University Press.
- LINGARD, L., ALBERT, M. & LEVINSON, W. 2008. Grounded theory, mixed methods, and action research. *BMJ*, 337, a567.
- LITTLE, P., DORWARD, M., WARNER, G., STEPHENS, K., SENIOR, J. & MOORE, M. 2004. Importance of patient pressure and perceived pressure and perceived medical need for investigations, referral, and prescribing in primary care: nested observational study. *BMJ*, 328(7437), 444.
- LUCAS, P. J., CABRAL, C., HAY, A. D. & HORWOOD, J. 2015. A systematic review of parent and clinician views and perceptions that influence prescribing decisions in relation to acute childhood infections in primary care. *Scandinavian Journal of Primary Health Care*, 33, 11-20.
- LYON, R. C., TAYLOR, J. S., PORTER, D. A., PRASANNA, H. R. & HUSSAIN, A. S. 2006. Stability profiles of drug products extended beyond labeled expiration dates. *Journal of Pharmaceutical Sciences*, 95, 1549-60.
- MALINOWSKI, B. 1922. *Argonauts of the Western Pacific: An Account of Native Enterprise and Adventure in the Archipelagos of Melanesian New Guinea*, London, UK, Routledge.
- MANGIONE-SMITH, R., MCGLYNN, E. A., ELLIOTT, M. N., KRIGSTAD, P. & BROOK, R. H. 1999. The relationship between perceived parental expectations and pediatrician antimicrobial prescribing behavior. *Pediatrics*, 103(4), 711-718.
- MARINER, J. C. & PASKIN, R. 2000. Manual on participatory epidemiology: Methods for the collection of action-oriented epidemiological intelligence. In: NATIONS, F. A. A. O. O. T. U. (ed.). Rome, Italy: FAO.
- MARTIN, L. R., WILLIAMS, S. L., HASKARD, K. B., DIMATTEO, M. R. 2005. The challenge of patient adherence. *Therapeutics and Clinical Risk Management*, 1, 189-199.
- MASON, J. 2006. Mixing methods in a qualitatively driven way. *Qualitative Research*, 6(1), 9-25.
- MATEUS, A. L. P., BRODBELT, D. C., BARBER, N. & STARK, K. D. C. 2014. Qualitative study of factors associated with antimicrobial usage in seven small animal veterinary practices in the UK. *Preventive Veterinary Medicine*, 117, 68-78.
- MAY, E. M., HUNTER, B. A. & JASON, L. A. 2017. Methodological Pluralism and Mixed Methodology to Strengthen Community Psychology Research: An Example from Oxford House. *Journal of Community Psychology*, 45, 100-116.
- MAY, T. 2002. *Qualitative Research in Action*, London, SAGE Publications.

- MCGUIRE, J., MORTON, L. W. & CAST, A. D. 2013. Reconstructing the good farmer identity: shifts in farmer identities and farm management practices to improve water quality. *Agriculture and Human Values*, 30(1), 57-69.
- MCKENZIE, B. A. 2014. Veterinary clinical decision making: cognitive biases, external constraints and strategies for improvement. *Journal of the American Veterinary Medical Association*, 244(3), 271-276.
- MEEK, A. H., MARTIN, S. W., STONE, J. B., MCMILLAN, I., BRITNEY, J. B. & GRIEVE, D. G. 1986. The relationship among current management systems, production, disease and drug usage on Ontario dairy farms. *Canadian Journal of Veterinary Research*, 50, 7-14.
- MENENDEZ GONZALEZ, S., STEINER, A., GASSNER, B. & REGULA, G. 2010. Antimicrobial use in Swiss dairy farms: Quantification and evaluation of data quality. *Preventive Veterinary Medicine*, 95, 50-63.
- MERLE, R., HAJEK, P., KAESBOHRER, A., HEGGER-GRAVENHORST, C., MOLLENHAUER, Y., ROBANUS, M., UNGEMACH, F.-R. & KREIENBROCK, L. 2012. Monitoring of antibiotic consumption in livestock: A German feasibility study. *Preventive Veterinary Medicine*, 104, 34-43.
- MERLE, R., ROBANUS, M., HEGGER-GRAVENHORST, C., MOLLENHAUER, Y., HAJEK, P., KASBOHRER, A., HONSCHA, W. & KREIENBROCK, L. 2014. Feasibility study of veterinary antibiotic consumption in Germany - comparison of ADDs and UDDs by animal production type, antimicrobial class and indication. *BMC Veterinary Research*, 10, 7.
- METCALFE, J. W. 2009. Microbiological Quality of Drug Products after Penetration of the Container System for Dose Preparation Prior to Patient Administration. *American Pharmaceutical Review* [Online]. [Accessed 1st December 2018].
- MILLS, H. L., TURNER, A., MORGANS, L., MASSEY, J., SCHUBERT, H., REES, G., BARRETT, D., DOWSEY, A. & REYHER, K. K. 2018. Evaluation of metrics for benchmarking antimicrobial use in the UK dairy industry. *Veterinary Record*, 182, 379-379.
- MORRIS, C., HELLIWELL, R. & RAMAN, S. 2016. Framing the agricultural use of antibiotics and antimicrobial resistance in UK national newspapers and the farming press. *Journal of Rural Studies*, 45, 43-53.
- MORRIS, P. 2012. *Blue Juice: Euthanasia in Veterinary Medicine*, USA, Temple University Press.
- MULLARKEY, M., DUFFY, A. & TIMMINS, F. 2011. Trust between nursing management and staff in critical care: a literature review. *Nursing in Critical Care*, 16(2), 85-91.
- NATIONAL HEALTH SERVICE 2017. Prescriptions Dispensed in the Community - Statistics for England 2006-2016. In: STATISTICS, N. (ed.). <https://digital.nhs.uk/data-and-information/publications/statistical/prescriptions-dispensed-in-the-community/prescriptions-dispensed-in-the-community-statistics-for-england-2006-2016-pas>. [Accessed 1st December 2018]
- NATIONAL HEALTH SERVICE 2018. Practice Level Prescribing in England: a summary. <https://digital.nhs.uk/data-and-information/areas-of-interest/prescribing/practice-level-prescribing-in-england-a-summary>. [Accessed 1st December 2018]
- NATIONAL OFFICE OF ANIMAL HEALTH. 2018a. *NOAH Animal Medicines Best Practice training* [Online]. <https://www.noah.co.uk/farmer-training/>. [Accessed 1st December 2018]
- NATIONAL OFFICE OF ANIMAL HEALTH 2018b. *NOAH Compendium of Datasheets for Animal Medicines* 2018. <http://www.noahcompendium.co.uk/datasheets>. [Accessed 1st December 2018]
- NICHTER, M. 1980. The layperson's perception of medicine as perspective into the utilization of multiple therapy systems in the Indian context. *Social Science and Medicine*, 14(4), 225-233.
- NICKERSON, R. S. 1998. Confirmation Bias: A Ubiquitous Phenomenon in Many Guises. *Review of General Psychology*, 2(2), 175-220.

- NOAH. 2017. *Estrumate® 250 µg/ml Solution for Injection Datasheet* [Online]. <http://www.noahcompendium.co.uk/?id=-461852>. [Accessed 25th May 2018].
- NOBREGA, D. B., DE BUCK, J., NAQVI, S. A., LIU, G., NAUSHAD, S., SAINI, V. & BARKEMA, H. W. 2017. Comparison of treatment records and inventory of empty drugcontainers to quantify antimicrobial usage in dairy herds. *Journal of Dairy Science*, 100(12), 9736-9745.
- O'CATHAIN, A., MURPHY, E. & NICHOLL, J. 2007. Why, and how, mixed methods research is undertaken in health services research in England: a mixed methods study. *BMC Health Services Research*, 7, 85.
- O'CATHAIN, A., THOMAS, K. J., DRABBLE, S. J., RUDOLPH, A. & HEWISON, J. 2013. What can qualitative research do for randomised controlled trials? A systematic mapping review *BMJ Open*, 3, e002889
- O'NEILL, J. 2016. Tackling Drug Resistant Infections Globally: Final report and recommendations. *The Review on Antimicrobial Resistance*.
- O'REILLY, K. 2012. *Ethnographic methods*, Oxon, UK, Routledge.
- OGUNSHE, A. & ADINMONYEMA, P. 2014. Evaluation of bacteriostatic potency of expired oral paediatric antibiotics and implications on infant health. *Pan African Medical Journal*, 19, 378.
- OMA, K. A. 2010. Between trust and domination: social contracts between humans and animals. *World Archaeology*, 42, 175-187.
- ONDRAK, J. D., JONES, M. L. & FAJT, V. R. 2015. Temperatures of storage areas in large animal veterinary practice vehicles in the summer and comparison with drug manufacturers' storage recommendations. *BMC Veterinary Research*, 11, 248.
- ORTMAN, K. & SVENSSON, C. 2004. Use of antimicrobial drugs in Swedish dairy calves and replacement heifers. *Veterinary Record*, 154, 136-140.
- PARDON, B., CATRY, B., DEWULF, J., PERSOONS, D., HOSTENS, M., DE BLEECKER, K. & DEPREZ, P. 2012. Prospective study on quantitative and qualitative antimicrobial and anti-inflammatory drug use in white veal calves. *Journal of Antimicrobial Chemotherapy*, 67, 1027-38.
- PIKE, T. 2008. Understanding Behaviours in a Farming Context: Bringing theoretical and applied evidence together from across DEFRA and highlighting policy relevance and implications for future research. . *DEFRA Agricultural Change and Environment Observatory Discussion Paper*.
- POIZAT, A., BONNET-BEAUGRAND, F., RAULT, A., FOURICHON, C. & BAREILLE, N. 2017. Antibiotic use by farmers to control mastitis as influenced by health advice and dairy farming systems. *Preventive Veterinary Medicine*, 146, 61-72.
- POL, M. & RUEGG, P. L. 2007. Treatment practices and quantification of antimicrobial drug usage in conventional and organic dairy farms in Wisconsin. *Journal of Dairy Science*, 90, 249-261.
- POOL, R. & GEISSLER, W. 2005. *Medical Anthropology*, UK, McGraw-Hill Education.
- POPE, C. & MAYS, N. 2006. *Qualitative research in healthcare*, Oxford, UK, Blackwell Publishing Ltd.
- PUBLIC HEALTH ENGLAND & DEPARTMENT OF HEALTH 2015. Behaviour change and antibiotic prescribing in healthcare settings: Literature review and behavioural analysis. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/405031/Behaviour_Change_for_Antibiotic_Prescribing_-_FINAL.pdf. [Accessed 12th December 2018]
- R CORE TEAM 2012. R: A language and environment for statistical computing. <http://www.R-project.org/>: R Foundation for Statistical Computing, Vienna, Austria.
- RAYMOND, M. J., WOHRLE, R. D. & CALL, D. R. 2006. Assessment and promotion of judicious antibiotic use on dairy farms in Washington state. *Journal of Dairy Science*, 89, 3228-3240.
- RED TRACTOR ASSURANCE 2017. Red Tractor Assurance for Farms: Dairy Standards https://assurance.redtractor.org.uk/contentfiles/Farmers-6802.pdf?_id=636359680695407277, Version 4.0 Accessed May 25, 2018.

- RED TRACTOR ASSURANCE 2018. Responsible Use of Antibiotics on Red Tractor Dairy Farms. https://assurance.redtractor.org.uk/contentfiles/Farmers-6912.pdf?_636585117784901746 (Accessed 25/05/2018).
- REDDING, L. E., CUBAS-DELGADO, F., SAMMEL, M. D., SMITH, G., GALLIGAN, D. T., LEVY, M. Z. & HENNESSY, S. 2014. Comparison of two methods for collecting antibiotic use data on small dairy farms. *Preventive Veterinary Medicine*, 114, 213-222.
- REES, G. M., BARRETT, D. C., BULLER, H., MILLS, H. L. & REYHER, K. K. 2018. Storage of prescription veterinary medicines on UK dairy farms: a cross-sectional study. *Veterinary Record* [Online]. [Accessed 1st December 2018].
- REHMAN, T., GARFORTH, C., MCKEMEY, K., YATES, C. & RANA, R. 2008. Farmers' behavioural inclinations and their influence on the anticipated response to the reform of the common agricultural policy in England. *Journal of Farm Management*, 13, 22-28.
- REHMAN, T., MCKEMEY, K., YATES, C. M., COOKE, R. J., GARFORTH, C. J., TRANTER, R. B., PARK, J. R. & DORWARD, P. T. 2007. Identifying and understanding factors influencing the uptake of new technologies on dairy farms in SW England using the theory of reasoned action. *Agricultural Systems*, 94, 281-293.
- REIJ, C. & WATERS-BAYER, A. 2014. *Farmer Innovation in Africa: A Source of Inspiration for Agricultural Development*, USA, Routledge.
- RELUN, A., LEHEBEL, A., CHESNIN, A., GUATTEO, R. & BAREILLE, N. 2013. Association between digital dermatitis lesions and test-day milk yield of Holstein cows from 41 French dairy farms. *Journal of Dairy Science*, 96(4), 2190-2200.
- RESPONSIBLE USE OF MEDICINES IN AGRICULTURE ALLIANCE 2015. RUMA Guidelines: Responsible use of antimicrobials in cattle production. In: ALLIANCE, R. (ed.). https://www.ruma.org.uk/wp-content/uploads/2015/07/RUMA_antimicrobial_long_cattle_revised_2015.pdf. [Accessed 1st December 2018]
- RESPONSIBLE USE OF MEDICINES IN AGRICULTURE ALLIANCE 2017. Targets Task Force Report <https://www.ruma.org.uk/wp-content/uploads/2017/10/RUMA-Targets-Task-Force-Report-2017-FINAL.pdf>. [Accessed 1st December 2018]
- RICHENS, I. F., BRENNAN, M. L., WAPENAAR, W., HOBSON-WEST, P., WRIGHT, N. & O'CONNOR, H. 2013. Methods used to collect farmers' attitudes, motivators and barriers toward cattle production: a rapid review. *British Society of Animal Science and the Association of Veterinary Teaching and Research Work*, 4, 13.
- RICHENS, I. F., HOBSON-WEST, P., BRENNAN, M. L., LOWTON, R., KALER, J. & WAPENAAR, W. 2015. Farmers' perception of the role of veterinary surgeons in vaccination strategies on British dairy farms. *Veterinary Record*, 177, 465.
- RIGGINS, S. H. 1994. *The Socialness of Things. Essays on the Socio-Semiotics of objects*, Berlin, Mouton de Gruyter.
- RITTER, C., JANSEN, J., ROCHE, S., KELTON, D. F., ADAMS, C. L., ORSEL, K., ERSKINE, R. J., BENEDICTUS, G., LAM, T. J. & BARKEMA, H. W. 2017. Invited review: Determinants of farmers' adoption of management-based strategies for infectious disease prevention and control. *Journal of Dairy Science*, 100(5), 3329-3347
- ROYAL COLLEGE OF VETERINARY SURGEONS 2018. Practice Standards Scheme Farm Animal Module and Awards. <file:///C:/Users/gr14229/Chrome%20Local%20Downloads/farm-animal-modules-and-awards-v2-21-november-2018-pdf.pdf>. [Accessed 1st December 2018]
- ROYAL COLLEGE OF VETERINARY SURGEONS Updated 2018. Code of Professional Conduct for Veterinary Surgeons 4. Veterinary Medicines. <https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/veterinary-medicines/>. [Accessed 1st December 2018]

- SAINI, V., MCCLURE, J. T., LEGER, D., DUFOUR, S., SHELDON, A. G., SCHOLL, D. T. & BARKEMA, H. W. 2012. Antimicrobial use on Canadian dairy farms. *Journal of Dairy Science*, 95, 1209-1221.
- SAMORE, M. H., BATEMAN, K., ALDER, S. C., HANNAH, E., DONNELLY, S., STODDARD, G. J., HADDADIN, B., RUBIN, M. A., WILLIAMSON, J., STUTLS, B., RUPPER, R. & STEVENSON, K. 2005. Clinical Decision Support and Appropriateness of Antimicrobial Prescribing: A Randomized Trial. *Journal of the American Medical Association*, 294(18), 2305-2314.
- SANTMAN-BERENDS, I., LUTTIKHOLT, S., VAN DEN BROM, R., VAN SCHAIK, G., GONGGRIJP, M., HAGE, H. & VELLEMA, P. 2014. Estimation of the use of antibiotics in the small ruminant industry in The Netherlands in 2011 and 2012. *PLoS One*, 9, e105052.
- SAPOSNIK, G., REDELMEIER, D., RUFF, C. C. & TOBLER, P. N. 2016. Cognitive biases associated with medical decisions: a systematic review. *BMC Medical Informatics and Decision Making*, 16, 138.
- SAVAGE, J. 2000. Ethnography and Healthcare. *British Medical Journal*, 321, 1400-1402.
- SAWANT, A. A., SORDILLO, L. M. & JAYARAO, B. M. 2005. A survey on antibiotic usage in dairy herds in Pennsylvania. *Journal of Dairy Science*, 88, 2991-2999.
- SAWFORD, K., VOLLMAN, A. R. & STEPHEN, C. 2013. A focused ethnographic study of Alberta cattle veterinarians' decision making about diagnostic laboratory submissions and perceptions of surveillance programs. *PLoS One*, 8, e64811.
- SCHERPENZEEL, C. G., DEN UIJL, I. E., VAN SCHAIK, G., RIEKERINK, R. G., HOGEVEEN, H. & LAM, T. J. 2016. Effect of different scenarios for selective dry-cow therapy on udder health, antimicrobial usage, and economics. *J Dairy Sci*, 99, 3753-64.
- SECRETARY OF STATE 2001. Misuse of Drugs Regulations 2001 (S.I. 3998). United Kingdom.
- SEPPÄLÄ, T., LIPPONEN, J., PIRTILA-BACKMAN, A.-M. & LIPSANEN, J. 2011. Reciprocity of trust in the supervisor-subordinate relationship: The mediating role of autonomy and the sense of power. *European Journal of Work and Organizational Psychology*, 20, 755-778.
- SHAW, J. R., BONNETT, B. N., ADAMS, C. L. & ROTER, D. L. 2006. Veterinarian-client-patient communication patterns used during clinical appointments in companion animal practice. *Journal of the American Veterinary Medical Association*, 228(5), 714-721.
- SHEHADEH, M., SUAIFAN, G., DARWISH, R. M., WAZAIFY, M., ZARU, L. & ALJA'FARI, S. 2012. Knowledge, attitudes and behavior regarding antibiotics use and misuse among adults in the community of Jordan. A pilot study. *Saudi Pharmaceutical Journal*, 20, 125-33.
- SHOVE, E. & SOUTHERTON, D. 2000. Defrosting the Freezer: From Novelty to Convenience. A Narrative of Normalization. *Journal of Material Culture*, 5(3), 301-319.
- SPEKSNIJDER, D. C., JAARSMA, D. A. C., VERHEIJ, T. J. M. & WAGENAAR, J. A. 2015. Attitudes and perceptions of Dutch veterinarians on their role in the reduction of antimicrobial use in farm animals. *Preventive Veterinary Medicine*, 121, 365-373.
- STATENS SERUM INSTITUT & NATIONAL FOOD INSTITUTE 2018. DANMAP 2017 - Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food animals, food and humans in Denmark. <https://www.danmap.org/>. [Accessed 12th December 2018]
- STATHAM, J. & GREEN, M. 2015. Cattle veterinary services in a changing world. *Veterinary Record*, 176, 276-80.
- STEVENS, M., PIEPERS, S., SUPRE, K., DEWULF, J. & DE VliegHER, S. 2016. Quantification of antimicrobial consumption in adult cattle on dairy herds in Flanders, Belgium, and associations with udder health, milk quality, and production performance. *Journal of Dairy Science*, 99, 2118-30.
- SWINKELS, J. M., HILKENS, A., ZOCHÉ-GOLOB, V., KROMKER, V., BUDDIGER, M., JANSEN, J. & LAM, T. 2015. Social influences on the duration of antibiotic treatment of clinical mastitis in dairy cows. *Journal of Dairy Science*, 98, 2369-2380.

- TANG, K. L., CAFFREY, N. P., NOBREGA, D. B., CRRK, S. C., RONKSLEY, P. E. & BARKEMA, H. W. E. A. 2017. Restricting the use of antibiotics in food-producing animals and its associations with antibiotic resistance in food-producing animals and human beings: a systematic review and meta-analysis. *The Lancet Planetary Health*, 1(8), 316-327.
- TASHAKKORI, A. & TEDDLIE, C. 2010. *SAGE Handbook of Mixed Methods in Social and Behavioural Research*, London, UK, SAGE Publications, Inc.
- TAXIS, K. B., N. 2003. Causes of intravenous medication errors: an ethnographic study. *Quality and Safety in Health Care*, 12, 343-347.
- TENI, F. S., SURUR, A. S., BELAY, A., WONDIMSIGEGN, D., GELAYEE, D. A., SHEWAMENE, Z., LEGESSE, B. & BIRRU, E. M. 2017. A household survey of medicine storage practices in Gondar town, northwestern Ethiopia. *BMC Public Health*, 17(1), 238.
- THOM, D. H., WONG, S. T., GUZMAN, D., WU, A., PENKO, J., MIASKOWSKI, C. & KUSHEL, M. 2011. Physician trust in the patient: development and validation of a new measure. *Annals of Family Medicine*, 9(2), 148-154.
- TIMMERMAN, T., DEWULF, J., CATRY, B., FEYEN, B., OPSOMER, G., DE KRUIF, A. & MAES, D. 2006. Quantification and evaluation of antimicrobial drug use in group treatments for fattening pigs in Belgium. *Preventive Veterinary Medicine*, 74, 251-263.
- TIMONEN, V., FOLEY, G. & CONLON, C. 2018. Challenges when using Grounded Theory: A Pragmatic Introduction to Doing GT Research. *International Journal of Qualitative Methods*, 17, 1-10.
- TRAUFFLER, M., GRIESBACHER, A., FUCHS, K. & KOEFER, J. 2014. Antimicrobial drug use in Austrian pig farms: plausibility check of electronic on-farm records and estimation of consumption. *Veterinary Record*, 175, 402-U36.
- TSILIGIANI, I. G., DELGATTY, C., ALEGAKIS, A. & LIONIS, C. 2012. A household survey on the extent of home medication storage. A cross-sectional study from rural Crete, Greece. *European Journal of General Practice*, 18, 3-8.
- TURNER, J. & REYNOLDS, K. J. 2010. *The story of social identity. In: Rediscovering Social Identity: Key Readings*, New York, Psychology Press.
- VAARST, M., PAARUP-LAURSEN, B., HOUE, H., FOSSING, C. & ANDERSEN, H. J. 2002. Farmers' choice of medical treatment of mastitis in Danish dairy herds based on qualitative research interviews. *Journal of Dairy Science*, 85, 992-1001.
- VAARST, M., THAMSBORG, S. M., BENNEDSGAARD, T. W., HOUE, H., ENEVOLDSEN, C., AARESTRUP, F. M. & DE SNOO, A. 2003. Organic dairy farmers' decision making in the first 2 years after conversion in relation to mastitis treatments. *Livestock Production Science*, 80, 109-120.
- VAN DER GEEST, S., WHYTE, S. R. & HARDON, A. 1996. The anthropology of pharmaceuticals: a biographical approach. *Annual Review of Anthropology*, 25, 153-178.
- VAN DIJK, W., FABER, M. J., TANKE, M. A., JEURISSEN, P. P. & WESTERT, G. P. 2016. Medicalisation and Overdiagnosis: What Society Does to Medicine. *International Journal of Health Policy Management*, 5, 619-622.
- VERSI, E. 1992. "Gold standard" is an appropriate term. *BMJ*, 305(6846), 187.
- VET FUTURES PROJECT BOARD 2015. Taking Charge of our future: A vision for the veterinary profession for 2030. <https://www.vetfutures.org.uk/resource/vet-futures-report/> [Accessed 1st December 2018]
- VET TIMES 2018. Billions lost in growing illegal vet medicines market. <https://www.vettimes.co.uk/news/billions-lost-in-growing-illegal-vet-medicines-market-report/>. [Accessed 1st December 2018]
- VETERINARY MEDICINES DIRECTORATE 2014a. Code of Practice on the responsible use of animal medicines on the farm. *Veterinary Medicines Directorate*.
- VETERINARY MEDICINES DIRECTORATE 2014b. Veterinary Medicinal Residues in Food Information Sheet on How to Determine Withdrawal Periods

- <https://www.gov.uk/government/collections/animal-medicines-information-leaflets>. [Accessed 12th December 2018]
- VETERINARY MEDICINES DIRECTORATE 2015a. Advertise veterinary medicines legally. 1st June 2015 ed. <https://www.gov.uk/guidance/advertise-veterinary-medicines-legally>: VMD. [Accessed 12th December 2018]
- VETERINARY MEDICINES DIRECTORATE 2015b. The Cascade: prescribing unauthorised medicines. <https://www.gov.uk/guidance/the-cascade-prescribing-unauthorised-medicines> [Accessed 12th December 2018].
- VETERINARY MEDICINES DIRECTORATE 2015c. Retail of Veterinary Medicines. In: DIRECTORATE, V. M. (ed.). <https://www.gov.uk/guidance/retail-of-veterinary-medicines>. [Accessed 12th December 2018]
- VETERINARY MEDICINES DIRECTORATE 2016. Understanding the population correction unit used to calculate antibiotic use in food producing animals. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/580710/1101060-v1-Understanding_the_PCU_-_gov_uk_guidance.pdf. [Accessed 12th December 2018]
- VETERINARY MEDICINES DIRECTORATE 2017. UK Veterinary Antibiotic Resistance and Sales Surveillance Report UK-VARSS 2016. *Veterinary Medicines Directorate*.
- VETERINARY MEDICINES DIRECTORATE 2018a. List of registered SQPs. <https://www.vmd.defra.gov.uk/register/sqpreregister.aspx>. [Accessed 12th December 2018]
- VETERINARY MEDICINES DIRECTORATE 2018b. Product Information Database. <https://www.vmd.defra.gov.uk/ProductInformationDatabase/> [Accessed 12th December 2018]
- VETERINARY MEDICINES DIRECTORATE 2018c. UK Veterinary Antibiotic Resistance and Sales Surveillance Report UK-VARSS 2017. In: DIRECTORATE, V. M. (ed.).
- VETERINARY MEDICINES REGULATIONS 2013. The Veterinary Medicines Regulations. In: GOVERNMENT, U. (ed.) No. 2033. Westminster.
- VOGL, C. R., KUMMER, S., LEITGIEB, F., SCHUNKO, C. & AIGNER, M. 2017. *Keeping the Actors in the Organic System learning: The Role of Organic Farmers' Experiments*, Oakville, Canada, Apple Academic Press, Inc.
- WAHYUNI, D. 2012. The Research Design Maze: Understanding Paradigms, Cases, Methods and Methodologies *Journal of Applied Management Accounting Research*, 10, 69-80.
- WALTER, S. D., ELIASZIW, M. & DONNER, A. 1998. Sample size and optimal designs for reliability studies. *Statistics in Medicine*, 17(1), 101-110.
- WATSON, P. F. & PETRIE, A. 2010. Method agreement analysis: a review of correct methodology. *Theriogenology*, 73, 1167-79.
- WEISS, B. D. 2007. *Health literacy and patient safety: Help patients understand*, Chicago, USA, American Medical Association and AMA Foundation.
- WELCH, H. G., SCHWARTZ, L. & WOLOSHIN, S. 2012. *Overdiagnosed: Making People Sick in the Pursuit of Health*, Beacon Press.
- WHALEY, L. E., BUSINGER, A. C., DEMPSEY, P. P. & LINDER, J. A. 2013. Visit complexity, diagnostic uncertainty, and antibiotic prescribing for acute cough in primary care: a retrospective study. *BMC Family Practice*, 14, 120.
- WHITING, L. S. 2008. Semi-structured interviews: Guidance for novice researchers. *Nursing Standard*, 22, 35-40.
- WILLIAMS, P. D. & PAIXAO, G. 2018. On-farm storage of livestock vaccines may be a risk to vaccine efficacy: a study of the performance of on-farm refrigerators to maintain the correct storage temperature. *BMC Veterinary Research*, 14, 136.

- WILLOCK, J., DEARY, I. J., MCGREGOR, M. M., SUTHERLAND, A., EDWARDS-JONES, G., MORGAN, O., DENT, B., GRIEVE, R., GIBSON, G. & AUSTIN, E. 1999. Farmers' attitudes, objectives, behaviors, and personality traits: The Edinburgh Study of Decision Making on Farms. *Journal of Vocational Behavior*, 54, 5-36.
- WORLD HEALTH ORGANISATION 2016. Critically important antimicrobials for human medicine. *World Health Organisation*, 5th Revision.
- ZARGARZADEH, A. H., TAVAKOLI, N. & HASSANZADEH, A. 2005. A Survey on the Extent of Medication Storage and Wastage in Urban Iranian Households. *Clinical Therapeutics*, 27(6), 970-978.
- ZWALD, A. G., RUEGG, P. L., KANEENE, J. B., WARNICK, L. D., WELLS, S. J., FOSSLER, C. & HALBERT, L. W. 2004. Management practices and reported antimicrobial usage on conventional and organic dairy farms. *Journal of Dairy Science*, 87, 191-201.

Appendix 1: Participant information leaflet for medicine audit farms



Participant Information Sheet

Study title: Understanding on-farm medicine use in dairy cattle: Addressing the knowledge gap

We would like to invite you to participate in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish, and please do ask us if there is anything that is not clear.

What is the purpose of this study?

This study aims to bring about a greater understanding of the way medicines are used in dairy cattle. Currently little is known about what happens to prescribed medicines after they are sold by the veterinary practice. The focus of the study is to try and understand how medicines are used, the reasons why they are used as they are and whether this use is reflected by the veterinary sales data from your veterinary surgeon.

Why have I been invited?

You have been invited to participate in this study for one of the following reasons:

- a) You have been suggested as a suitable participant for this study by your veterinary practice
- b) You have been approached by the researchers directly because you fit the criteria for the study

There will be around 20-30 dairy farms in total recruited to this study.

Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason.

What will happen if I take part and what will I have to do?

Involvement in this study will be over a period of 12 months, from September 2016 – August 2017, during which time the researcher is likely to visit 4-6 times.

During the study you will be asked to:

- Complete a participant information questionnaire gathering data about your farming enterprise
- Participate in an in-depth interview with the researcher. This interview will last approximately 60-90 minutes. This interview will be audio-recorded using an encrypted dictaphone and transcribed for analysis. All data used from these interviews will be made anonymous and may include the use of anonymised quotes.
- Allow veterinary prescription data from your veterinary surgeon to be viewed. The researcher will collect data of all of the medicines prescribed to your farm over the course of a year, from September 2016-August 2017. No financial records or drug costs will be sought, the data used will include the name of the drug, formulation, volume sold and dates.
- Allow the contents of the medicine cabinet and any other areas where medicines are stored on the farm to be examined at intervals throughout the year. Photographs may be taken of relevant areas of medicine storage and use and other areas of the farm to help illustrate the research, where appropriate. These photographs will be anonymised.
- You will be asked to throw away all empty medicine packaging/bottles etc. into the bins provided for the course of the whole year. The researcher will examine the content of these bins every 2-3 months after which they can be emptied.
- Provide access to your medicine records and herd health plan for analysis

All of the data collected on the farm will be stored securely at the University of Bristol and will be completely confidential. Any names or identifying features will be removed from the data collected from this farm before it is made public.

The study is about gathering data about what happens on a day-to-day basis on your farm. This study will not provide guidance about medicine use, aim to reduce, influence or in any way change medicine use on your farm.

Will I be paid to take part in this study?

There is no payment for participation, however following participation in this study a small token of gratitude will be offered. This might be tickets to a national dairy show, a conference or gift tokens with a value in the region of £30-50

What are the possible disadvantages and risks of taking part?

There are no foreseen disadvantages or risks of taking part in this study. However suspected notifiable diseases, illegal practices or mistreatment of animals would require reporting to the relevant authority by the researcher, as they would by any other visitor to the farm.

What are the possible benefits of taking part?

We cannot promise that this study will provide any immediate benefits to you, however the information we get from this study will help to inform the agricultural community, veterinarians, those in research development and policy-makers about how veterinary medicines are being used across the dairy industry. Many people enjoy participation in research, particularly expressing their views during in-depth interviews.

Will my taking part in the study be kept confidential?

All information gathered about you and the farm will be handled in confidence by us. All data will be stored on encrypted computers or in locked cabinets at the University of Bristol. Audio-recordings of the interview will be made using an encrypted dictaphone. These interviews will be transcribed, coded and the results anonymised. Quotes from interviews may be used, but these will also be anonymous, any names or identifying features will be removed.

Data from this study will be available to genuine researchers upon request, and will be stored for 20 years. After this point it will be disposed of securely.

What will happen if I don't want to carry on with the study?

You can withdraw from this study at any time without giving a reason. The data collected up until the date of withdrawal will still be included in the study.

What will happen to the results of the research study?

It is intended that the results of this study will be published in the scientific literature, and presented at national and international conferences. Results may also be publicised through the agricultural press. A 'newsletter' giving an overview of the study results will be sent to you and all other participants once the study and analysis have been completed. You will also be invited to a meeting where the results will be presented. Your individual results will not be available.

Who is organising and funding the research?

This research forms the basis of a PhD project by Gwen Rees through the University of Bristol. The study has been funded by the Langford Trust, a charity promoting the practice, advancement and teaching of veterinary science.

Who has reviewed the study?

The University of Bristol Research Ethics Committee has reviewed this study

Where can I find out further information?

For any further information, please contact the lead researcher:

Gwen Rees

University of Bristol

Langford House

North Somerset

BS40 5DU

+44 7855 804270 gwen.rees@bristol.ac.uk

If you have any concerns related to your participation in this study please contact the Research Support Officer:

Dr. Christine Whiting +44 (0) 117 928 9296
--

c.v.whiting@bristol.ac.uk
--

Appendix 2: Participant information sheet for farms undergoing participant observation



Participant Information Sheet

(Participant Observation Farms)

Study title: Understanding on-farm medicine use in dairy cattle: Addressing the knowledge gap

We would like to invite you to participate in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish, and please do ask us if there is anything that is not clear.

What is the purpose of this study?

This study aims to bring about a greater understanding of the way medicines are used in dairy cattle. Currently little is known about what happens to prescribed medicines after they are sold by the veterinary practice. The focus of the study is to try and understand how medicines are used, the reasons why they are used as they are and whether this use is reflected by the veterinary sales data from your veterinary surgeon.

Why have I been invited?

You have been invited to participate in this study for one of the following reasons:

- c) You have been suggested as a suitable participant for this study by your veterinary practice
- d) You have been approached by the researchers directly because you fit the criteria for the study

There will be around 20-30 dairy farms in total recruited to this study, of which 3-5 will include year-long observation.

Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason.

What will happen if I take part, and what will I have to do?

Involvement in this study will be over a period of 12 months, from September 2016 – August 2017, during which time the researcher is likely to visit often and spend time on the farm observing normal daily routines.

During the study you will be asked to:

- Complete a participant information questionnaire gathering data about your farming enterprise
- Participate in an in-depth interview with the researcher. This interview will last approximately 60-90 minutes. This interview will be audio-recorded using an encrypted dictaphone and transcribed for analysis. All data used from these interviews will be made anonymous and may include the use of anonymised quotes.
- Allow the researcher to visit regularly to observe the normal routine administration of veterinary medicines and other daily work. This may include visiting during TB testing, while worming or vaccinating animals, foot trimming, during milking and at other periods.
- The researcher will be in regular telephone contact, in order to discuss any ongoing medicine and health issues and to arrange times and days to visit.
- Allow veterinary prescription data from your veterinary surgeon to be viewed. The researcher will collect data of all of the medicines prescribed to your farm over the course of a year, from September 2016-August 2017. No financial records or drug costs will be sought; the data used will include the name of the drug, formulation, volume sold and dates.
- Allow the contents of the medicine cabinet and any other areas where medicines are stored on the farm to be examined at intervals throughout the year. Photographs may be taken of relevant areas of medicine storage and use and other areas of the farm to help illustrate the research, where appropriate. These photographs will be anonymised.
- You will be asked to throw away all empty medicine packaging, bottles, etc. into the bins provided for the course of the whole year. The researcher will examine the content of these bins every 2-3 months, after which they can be emptied.
- Provide access to your medicine records and herd health plan for analysis

All of the data collected on the farm will be stored securely at the University of Bristol and will be completely confidential. Any names or identifying features will be removed from the data collected from this farm before it is made public.

The study is about gathering data about what happens on a day-to-day basis on your farm. This study will not provide guidance about medicine use, aim to reduce, influence or in any way change medicine use on your farm.

Will I be paid to take part in this study?

There is no payment for participation, however following participation in this study a small token of gratitude will be offered. This might be tickets to a national dairy show, a conference or gift tokens with a value in the region of £50-100

What are the possible disadvantages and risks of taking part?

There are no foreseen disadvantages or risks of taking part in this study. However suspected notifiable diseases, illegal practices or mistreatment of animals would require reporting to the relevant authority by the researcher, as they would by any other visitor to the farm.

What are the possible benefits of taking part?

We cannot promise that this study will provide any immediate benefits to you, however the information we get from this study will help to inform the agricultural community, veterinarians, those in research development and policy-makers about how veterinary medicines are being used across the dairy industry. Many people enjoy participation in research, particularly expressing their views during in-depth interviews.

Will my taking part in the study be kept confidential?

All information gathered about you and the farm will be handled in confidence by us. All data will be stored on encrypted computers or in locked cabinets at the University of Bristol. Audio-recordings of the interview will be made using an encrypted dictaphone. These interviews will be transcribed, coded and the results anonymised. Quotes from interviews may be used, but these will also be anonymous, any names or identifying features will be removed.

Data from this study will be available to genuine researchers upon request and will be stored for 20 years. After this point it will be disposed of securely

What will happen if I don't want to carry on with the study?

You can withdraw from this study at any time without giving a reason.

What will happen to the results of the research study?

It is intended that the results of this study will be published in the scientific literature and presented at national and international conferences. Results may also be publicised through the agricultural press. A 'newsletter' giving an overview of the study results will be sent to you and all other participants once the study and analysis have been completed. You will also be invited to a meeting where the results will be presented. Your individual results will not be available.

Who is organising and funding the research?

This research forms the basis of a PhD project by Gwen Rees through the University of Bristol. The study has been funded by the Langford Trust, a charity promoting the practice, advancement and teaching of veterinary science.

Who has reviewed the study?

The University of Bristol Research Ethics Committee has reviewed this study

Where can I find out further information?

For any further information, please contact the lead researcher:

Gwen Rees

+44 7855 804270 gwen.rees@bristol.ac.uk

If you have any concerns related to your participation in this study please contact the Research Support Officer:

Dr. Christine Whiting +44 (0) 117 928 9296 c.v.whiting@bristol.ac.uk
--

Appendix 3: Consent form



CONSENT FORM

Title of project: Understanding on-farm medicine use in dairy cattle:
Addressing the knowledge gap

Name of Researcher: Gwen Rees

Please initial ALL boxes

1. I confirm that I have read and understand the information sheet dated [09.05.2016] [Version number 1.2] for the above study. I have had the opportunity to consider the information, ask questions and have had those answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason
3. I understand that relevant veterinary and farm data, as described in the information sheet, which is collected during the study may be made available, in anonymised form, to genuine researchers upon request
4. I agree to the use of audio-recording equipment in this study and the possible use of anonymised quotes and photographs in any future publications
5. I agree to my veterinary surgeon being informed of my participation in this study
6. I agree to my veterinary medicine prescription data (excluding financial data) being made available by my veterinary surgeons for the purposes of this study
7. I agree to take part in the above study

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

Name of Participant

Date

Signature

Name of person taking consent

Date

Signature

Appendix 4: Farmer recruitment leaflet (North Somerset)

Understanding On-Farm Medicine Use in Dairy Cattle



Involve your farm in important new research!

The way farmers use veterinary medicines has never been properly understood. With the current media interest in antibiotic resistance, it is likely things are going to change and milk buyers are bringing in new medicine guidelines more and more often. We want those guidelines to be fair and to be based on the facts. This project will study how well we can estimate what medicines are used in dairy cattle, and help understand why medicines and records are used the way they are.

What does it involve?

One year of placing all of your empty medicine containers, bottles and intramammary tubes in a special bin, as well as providing access to medicine records.

What do you gain?

As well as being involved in important research aimed to help the dairy industry, we will dispose of all of your empty medicines for a year, as well as provide a small thankyou at the end – tickets to the Bath and West Dairy show after the project is complete.

Who do we need?

Dairy farms, of ANY size and management type
in North Somerset

If interested, please contact:
Gwen Rees
gwen.rees@bristol.ac.uk
07855 804270



Langford
TRUST
FOR ANIMAL
HEALTH & WELFARE



Appendix 5: Structured farm management and demographic questionnaire



Date: 26/02/2016

Version: 1.3

FARMER QUESTIONNAIRE

The following data will be used as part of the study **“Understanding on-farm medicine use in dairy cattle: Addressing the knowledge gap”**

This questionnaire is to be asked verbally and completed by the researcher during the first visit to the farm.

NAME..... DATE.....

FARM NAME AND ADDRESS

.....
.....
.....

NAME OF VETERINARY PRACTICE.....

NAME OF VETERINARY SURGEON.....

Farmer and Household Characteristics

Age:

18-30, 31-40, 41-50, 51-60, 61+

Formal education level:

None, O level/GCE/GCSE, A Level, NVQ/ Diploma/Agricultural College, University degree, Postgraduate qualification

Gender:

Marital status:

Children? (Please include ages)

Do any family members carry out work on the farm?

Number full-time employees:

Number of part-time employees:

Herd statistics:

Number of cows currently in milk	
Number of dry cows	
Number of breeding bulls	
Number of in-calf heifers	
Number of yearling heifers	
Number of replacement heifers 8 weeks - 12 months	
Number of replacement heifer calves 0-8 weeks	
Number of other calves 0-8 weeks	
Number of male or beef-cross cattle 8 weeks – 12 months	
Number of male or beef-cross cattle over 12 months	
Other cattle (beef) – detail age and breed	
Number of sheep/goats	
Number of pigs	
Number of horses/donkeys	
Number of alpacas	
Any other stock on enterprise	

Other businesses or diversification	
Grazing land available (hectares)	
Cropping land available to grow forage (hectares)	
Silage	
Maize	
Whole crop	
Wheat	
Other	

Production

Aim of production: (i.e. liquid milk/cheese/ice-cream/organic)	
Total annual milk sales	
Average 305-day milk yield (L)	
Annual yield/cow (L)	
Milk price (ppl) (average for last 12 month)	
Average Somatic Cell Count	
Average Bactoscan	
Average milk fat %	
Average protein %	
Parlour type and size	
How many times are the cows milked daily?	
Milking cow nutrition: e.g. silage/TMR/grass/concentrate in-parlour	
Dry cow nutrition:	

Housing – description (include milking herd, dry cows, youngstock and calves)	
---	--

Fertility

Average age at first calving	
Average calving-to-conception interval (days)	
Dry cow period length	
AI or natural service?	AI / Natural service
Average no. serves/conception	
100-day in-calf rate	
200-day in-calf rate	
300-day empty rate	
Routine fertility visit? Frequency	Y/N

Health

Annual vet spend (£)	
Herd health plan? Frequency of review	Y/N
Health benchmarking	Y/N
Cull rate	
Death rate	
Describe dry cow management (blanket/selective)	Blanket / Selective
What is the replacement policy?	

Where are cattle sourced from?	
Which animals are vaccinated, and against what?	
Calves	
Heifers	
Adult Cows	
Are new stock quarantined?	Y / N
Does the herd have high health status?	Y / N
What is the herd status for?	
IBR	
BVD	
Lepto	
TB	
Johne's	
Respiratory disease in calves (cases/100/year)	
Gastrointestinal disease in calves (cases/100/year)	
Clinical mastitis (cases/100 cows/year)	
Lameness (cases/100 cows/year)	

Appendix 6: Initial visit checklist



Bin Audit Farm Enrolment Visit Checklist

General:

1. Clean boots and coveralls
2. Bucket, brush and soap
3. Pen & notebook
4. Camera
5. Consent form
6. Extra copies of participant info sheet (will have been sent out before)
7. 1-2 big bins plus 1 small bin for parlour (or as discussed)
8. Sharps bin
9. Medicine cupboard audit sheet
10. Farm identification labels
11. Questionnaire / laptop for structured questionnaire
12. Signs and sticky tape

On Farm:

1. Place bins as agreed with farmer
2. Stick up signs
3. Audit medicines cupboard and anywhere else drugs may be stored
4. Get farmer to complete consent forms and questionnaire
5. Record day book/medicine book use

On Return:

1. Label all worksheets with farm identification
2. Upload worksheets to computer database and file securely

Appendix 7: Medicine bin reminder signs placed on participating farms

MEDICINE BIN

PLEASE PLACE **ALL** USED MEDICINE CONTAINERS IN THIS BIN

STOP!!!

Please use the

MEDICINE BIN

Please DO place in these bins:

ALL empty medicine bottles

ALL used intra-mammary tubes

ALL used eye tubes

ALL used medicine containers

ALL expired or waste medicine

ALL used vaccine bottles

ALL wormers, calcium bottles etc



Please DO NOT place in these bins:

Needles

Syringes

Cardboard outer-boxes

General rubbish



Appendix 8: Bin Audit Farm visit checklist



Bin Audit Farm Visit Checklist

General:

13. Clean boots and coveralls
14. Bucket, brush and soap
15. Pen
16. Laptop
17. Camera
18. Notebook for general comments/observations

Drug Use Recording:

1. Box of 12 plastic clinical waste binbags
2. Farm identification labels (at least 12 per farm)
3. Spare sharps container (in case needs exchanging)
4. **Bin Audit Tally Worksheet**

On Farm:

6. Empty contents of bins into bags
7. Check if sharps bin needs changing
8. Record day book/medicine book use
9. Check farmer happy with bin use and bin number/location

On Return:

3. Process binbags according to protocol
4. Enter all medicine waste into dedicated farm spreadsheet
5. Upload worksheets to computer database and file securely

Appendix 9: Semi-structured in-depth interview topic guide

In-depth interview guide

(Semi-structured – topic guides only)

Introduction:

“This is an informal conversation so that I can try to understand how you feel and what you think about medicine use on your farm, and on farms in general. I have some questions and areas I’d like to ask about, but at any point you may say anything you think is relevant and there is no fixed structure. It should take around an hour, and at the end you can add anything else you would like to say. This interview will be recorded using this dictaphone, but if you want it turned off at any time I will agree to do so. Does that sound OK?”

TOPIC GUIDE

General intro

Did you always know you would be a dairy farmer?

Can you tell me about some of the positive and negative things about farming?

How do you see this farm looking in the future? *5 years, 10 years, 20 years?*

Animal Health

How would you describe the health of the animals on the farm?

How much of a difference do you think you make to the health and welfare of the animals on your farm?

How do you assess the health of your animals? (*Tools/ computer/ benchmarking/ “just know”/ veterinary input?*)

Can you describe the culling policy on your farm?

Medicine use

Who makes the treatment decisions on farm?

How do you decide which medicines to use when? Do you get advice from anyone?

Who gives the treatments – do they always do what it says in health plan?

Doses/ course length – how do you decide how much or how long? Do you ever change this depending on the situation?

How full do you like to keep your medicine cupboard? Why?

Where do you feel most of your medicine spend goes? And the most antibiotics?

Do you think you could use less medicines?

What are your thoughts about using vaccines?

A lot of farms are using medicines that have gone out of date – what do you think about that?

Do you use antibiotic footbaths?

Veterinary relationship

How often do you see the vet in a given year? Is this usually for routine visits or for emergencies?

How would you describe your relationship with your vet? What do you use them for and how do they contribute to the running of your farm?

- *Just a conduit for medicine, or mostly for advice?*
- *Health planning or emergency treatment*
- *One vet or many?*
- *What about new graduates*

What information does the vet provide about the medicines sold to you? *Which to use, what dose, how long for?*

- *Do you find this information useful??*
- *Is it clear? Easy to understand and utilise?*
- *How would you prefer to get this information about the medicines?*

Medicine recording, storage, disposal

How do you store medicine on your farm? Why? What about fridge goods?

What about recording use? Where do you record what you use?

Do you find the medicines book a useful way of recording medicine use? Does anyone look at it?

Do you tend to use everything that the vet sells you, or does some go to waste?

What happens to waste/excess drugs?

In an ideal world, how would you like to record medicine use on the farm?

Do you think technology will make a difference to this in the future?

What would you do differently/change to improve recording medicine use?

- *Make it easier/ more accurate/more useful*

Is there anything else you'd like to say, or anything important you think we haven't covered?

Appendix 10: Screenshot of prescription veterinary medicine database for medicines licensed for use in cattle, adapted from the veterinary medicines directorate's product information database

[illegible]

Appendix 11: Screenshot example of farm medicine audit database developed for data entry of prescription veterinary medicines during medicine cupboard inventories and medicine waste bin audits

	A	R	S	T	U	V	W	X	Y	Z
Medicine	Expired Day 2	Total Volume Dg	Number packs Dg	Expired Day 3	Total Volume Dg	Number packs Dg	Expired Day 4	Total Volume Dg	Number packs Dg	
ACEON 50 micrograms/ml Solution for Inje										
81 Alampin LA 300 Solution for Injection 300 r										
367 Bovilis BVD Suspension for Injection for Cat			0	300	0	0	2	0	60	
454 Canineve 50 mg/ml Solution for Injection fo						0		0	150	
495 Cemay 50 mg/ml Suspension for Injection fo			0	3	0	0	113	0	39	
499 Cepharuard DC 150 mg Intramammary Oint			0	198	0	0		0		
502 Cereprox 180 mg/ml Suspension for Injec			0	1	0		66	0	40	
503 Cephalock 2.6g Intramammary Suspension f			0	135	0	0		0	40	
611 Combivax Suspension for Injection		1								
657 Cyclix 250 microgram/ml Solution for Inje										
710 Deafect 2 mg/ml Solution for Injection for									20	
792 Duplathim 15 Injectable Solution Trimethopr			0	2	0					
899 Ergemycin Spray, 25 mg/ml, Cutaneous Spr			0	12	0	0	6	0	4	
985 Estumate Solution for Injection										
1003 Excedel Flow, 50 mg/ml, Suspension for Inje									60	
1038 Finaflyn 50 mg/ml Solution for Injection			0	1	0				30	
1188 Fosson 20% w/v Solution for Injection									20	
1250 Halocur 0.5 mg/ml Oral Solution for Calves			0	4	0				500	
1286 Imester			0	117	0	0	52	0		
1351 Mastiplan LC, 300 mg/20 mg (Cefapirin/Pre			0	359	0	0	192	0	12	
1572 Metacam 20 mg/ml Solution for Injection fo			0	8.5	0	0	5.5	0	110	
1581 Metecure 500 mg Intravenous Suspension									1	
1651 Naxcel 200 mg/ml Suspension for Injection			0	2	0	0	1	0		
1761 Noctidne 24 Solution for Injection			0			0	1	0		
1806 Opticore Eye Ointment 1% w/v			0	1	0				1	
1845 Oxydacin 5, 10 iu/ml, Solution for Injection			0	2	0					
1880 Pen 8 Strept Suspension for Injection			0	11	0	0	1	0	50	
2302 Strinacin II Tablets			0	1	2	0	1	0	23	
2467 Tylen 200, 200 mg/ml Solution for Injection			0	2	0					
2662 Zactran 150 mg/ml Solution for Injection fo			0	3	0	0	2	0	50	
2707										

Appendix 12: Individual farm medicine audit reports example



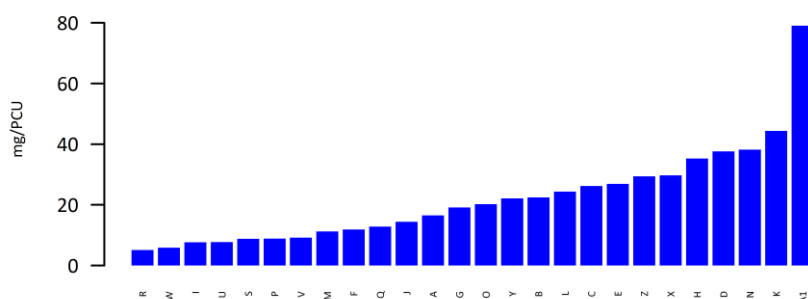
Medicine Use in Dairy study – Individual report FARM A

Thank you once again for being part of the medicine use in dairy study, which has given us valuable data that can be used to inform medicine use policies and academic research in the future.

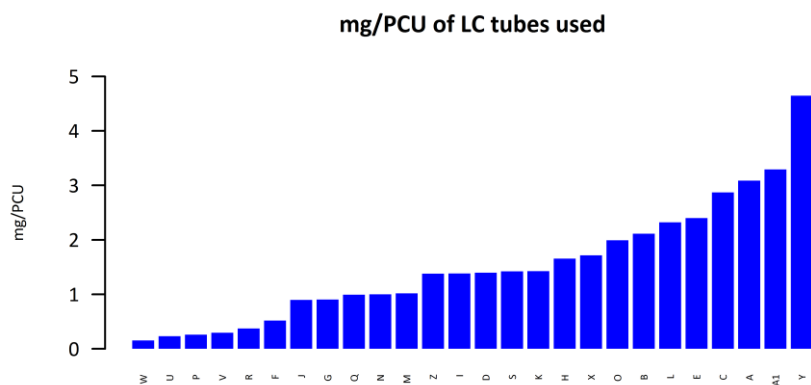
Please find below some results showing where your farm lies when compared with the other farms enrolled on the project. Your farm ID is **A**. Please note this is for interest only, because all farms were very different, with different breeds, calving patterns and levels of production.

At the end of this report is your farm's individual report, showing the amount of each medicine used when recorded by vet sales data, by medicine waste bin and by on-farm medicine records.

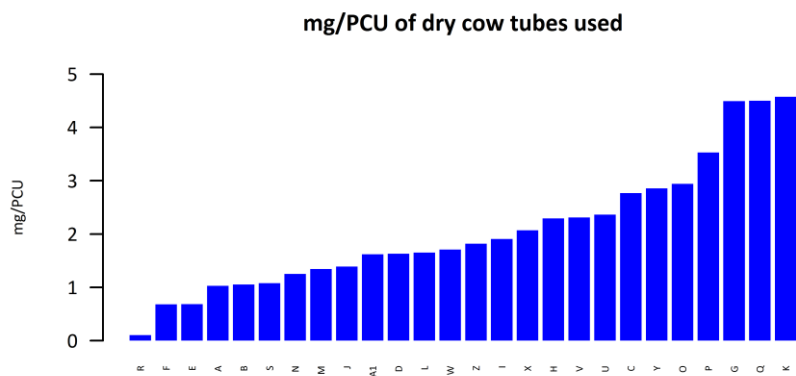
mg/PCU of injectable antibiotic used



This is the total amount of antibiotic used per kg of animal on your farm for injectable antibiotics.



This is the total amount of antibiotic used per kg of animal on your farm for lactating cow tubes.



This is the total amount of antibiotic used per kg of animal on your farm for dry cow tubes.

Medicine	Total use in 12 months based on bins		Total Use in 12 months based on vet sales		Total use in 12 months based on medicine book	
					Units	
ACEGON 50 micrograms/ml Solution for Injection for Cattle	22	5	0	ml		
Alamycin LA 300 Solution for Injection 300 mg/ml	0	60	0	ml		
Bovilis BVD Suspension for Injection for Cattle	300	0	0	doses		
Carprive 50 mg/ml Solution for Injection for Cattle	100	0	0	ml		
Cemay 50 mg/ml Suspension for Injection for Pigs and Cattle	1700	710	1700	ml		
Cephaguard DC 150 mg Intramammary Ointment	694	736	760	tubes		
Ceporex 180 mg/ml Suspension for Injection for Cattle, Cats and Dogs	100	0	100	ml		
CeptraLock 2.6g Intramammary Suspension for Cattle	576	560	0	tubes		
CombiClav Suspension for Injection	90	70	100	ml		
Cyclix 250 microgram/ml Solution for Injection for Cattle	40	0	0	ml		
Dexa-ject 2 mg/ml Solution for Injection for Cattle, Horses, Pigs, Dogs and Cats	0	40	0	ml		
Duphatriin IS Injectable Solution Trimethoprim 40 mg and Sulfadiazine 200 mg Solution for Injection	300	300	100	ml		
Engemycin Spray, 25 mg/ml, Cutaneous Spray, Suspension for Cattle, Sheep and Pigs	44	0	60	cans		
Estrumate Solution for Injection	2	4	0	ml		
Excenel Flow, 50 mg/ml, Suspension for Injection for Pigs and Cattle	0	0	0	ml		
Finadyne 50 mg/ml Solution for Injection	100	135	0	ml		
Foston 20% w/v Solution for Injection	150	25	0	ml		
Halocur 0.5 mg/ml Oral Solution for Calves	2500	0	3500	ml		
Imrester	246	0	0	doses		
Mastiplan LC, 300 mg/20 mg (Cetapirin/Prednisolone), Intramammary Suspension for Lactating Cows	1146	2064	1140	tubes		
Metacam 20 mg/ml Solution for Injection for Cattle, Pigs and Horses	3820	1980	2000	ml		
Metricure 500 mg Intrateirine Suspension	0	0	46	tubes		
Naxcel 200 mg/ml Suspension for Injection for Cattle	800	525	825			
Norodine 24 Solution for Injection	490	432	335			
Optidox Eye Ointment 16.7% w/w	2	1	8			
Oxytocin-5, 10 iu/ml, Solution for Injection	75	0	0			
Pen & Strep Suspension for Injection	2380	1900	2825			
Strinacin II Tablets	159	0	13			
Tylan 200, 200 mg/ml Solution for Injection	590	405	0			
Zactran 150 mg/ml Solution for Injection for Cattle and Pigs	985	0	1300			